OUTCOME ANALYSIS AND SURVEILLANCE OF INFRA INGUINAL ARTERIAL BYPASS GRAFT

Dissertation submitted in partial fulfillment of the requirement for the degree of

M.Ch (VASCULAR SURGERY) – BRANCH – VIII

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CERTIFICATE

This is to certify that this dissertation entitled **"OUTCOME ANALYSIS AND SURVEILLANCE OF INFRA INGUINAL ARTERIAL BYPASS GRAFT"** is a bonafide record of the research work done by **Dr. D. Ashok Kumar**, for the award of M.Ch., Vascular Surgery, under the supervision of **Prof. M.RAJKUMAR, MS, DNB, MCH,** Professor & Head, Department of Vascular Surgery, Government Stanley Medical College & Hospital, Chennai-1. I also certify that this dissertation is the result of the independent work done by the candidate.

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DECLARATION

I solemnly declare that this dissertation **"OUTCOME ANALYSIS AND SURVEILLANCE OF INFRA INGUINAL ARTERIAL BYPASS GRAFT"** was prepared by me in the Department of Vascular Surgery, Government Stanley Medical College & Hospital, Chennai under the guidance and supervision of **Prof. M. RAJKUMAR, MS, DNB, M.Ch**., Professor & Head, Department of Vascular Surgery, Government Stanley Medical College & Hospital, Chennai-1. This dissertation is submitted to the Tamil Nadu Dr.MGR Medical University, Chennai, in partial fulfillment of the University requirements for the award of degree of M.Ch. Vascular Surgery.

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INTRODUCTION

Infrainguinal bypass surgery in Chronic Limb Ischemia is the mainstay of therapeutic interventions aimed at limb salvage. The outcome of surgery is the chief determinant of limb salvage and is affected by many factors which can be modifiable factors (Smoking, Obesity, Hypertension, Lipids, Glycaemic control) and non modifiable factors (Age, Gender, Ethnicity, Family history). Since 1949, when Kunlin introduced the femoropopliteal bypass graft with saphenous vein, several centers have reported their results. Patency rates at 30 days have varied from 76% to 96%[1]. Cumulative five-year patency has varied from 60% to 76%.

Arterial disease of the lower limbs includes conditions such as inflammatory arteritis, TAO, vasospastic disorders and medial calcification. However, by far the commonest cause of Peripheral Arterial Occlusive Disease (PAOD) is Atherosclerosis which consists of slow accumulation of lipids and fibrosis in the arterial intima. The interaction between environmental and genetic factors accentuates the development and progression of occlusive vascular disease, involving one or more major vessels of the lower limb with an increased risk of acute limb threatening or life threatening ischemia. Patients in our population present with characteristic features of TAO in addition that they have occlusive disease in the medium and larger sized arteries including the femoral and iliac arteries. The incidence of disease in these proximal vessels seems to be particularly high in our population, contrary to disease definitions elsewhere in the world.

Arterial reconstruction especially with infrainguinal grafts for peripheral arterial occlusive disease continues to provide a significant challenge for vascular surgeons.

Graft surveillance refers to periodic evaluation of the grafts by means of tests that may involve special instrumentation, by which an abnormal result, suggest, the presence of pathology .By graft surveillance, failing grafts can be identified and corrective measures can be taken at appropriate time to improve graft patency.

Evaluation of patients with infrainguinal grafts has clearly demonstrated the factors that will affect the long term patency of vascular conduits .The patency of vascular grafts mandates a protocol of postoperative surveillance to identify grafts at risk of thrombosis since bypass graft occlusion is associated with significantly morbidity and limb loss. The correction of lesions before graft thrombosis can have a significant impact on long term patency. Analysis of the intensity of post-operative non-invasive surveillance, and their efficacy will be reviewed. . The patency rates have been related to clinical severity of ischemia, run-off, diabetes and diameter of vein.

The diameter of the stenosis, therefore, is far more important than its length. When the lesion responsible for a stenosis is axi-symmetric, a 75% area reduction corresponds to a 50% diameter reduction. Stenoses of this magnitude seen on arteriography are frequently labeled “critical” or “hemodynamically significant.” In order to clarify the natural history of graft failure ,the importance of graft surveillance has inspired me to conduct this study

Factors vary depending on the interval in the follow-up period and factors adversely affecting 30 day patency are primarily technical in nature and are related to

surgical technique. Such factors are best prevented and can often be identified by intraoperative evaluation. In the time period between 1 month and 12 months fibrointimal hyperplasia in a variety of forms is the primary cause of graft failure. Beyond 12 months the disease progression in both the inflow and outflow vessels and the conduit degenerative changes results in graft failure.

This study is planned to review the factors that will influence the outcome of infrainguinal bypass in CLI and to identify those factors that are modifiable, which will help in improving the outcome of the procedures and improve the patency of the graft and limb salvage rate.

Efficacy of post-operative medical therapy is also reviewed.

AIM

- To analyse the outcome of infra-inguinal arterial revascularisation procedures.
- To study the influence of risk factors.
- To identify failing graft.

MATERIALS AND METHODS

- **Prospective study**

- **Study period**: January 2010 to January 2012 in 56 patients

- **Patients selection** :

Case records of all patients admitted with the clinical diagnosis of for critical lower limb ischemia and severe disabling claudication who underwent femoropopliteal bypass procedures and tibial artery bypass procedures were analysed .

All patients were evaluated with proper clinical history, physical examination and pre operative CT angiogram was performed in all patients to assess the occlusive pattern and fiow limiting lesions, status of femoral ,popliteal artery and distal arteries run off status and the lesions were classified as per TASC 2007 classification. All patients with TASC C and D lesions and few selected patients with TASC B lesions were enrolled.

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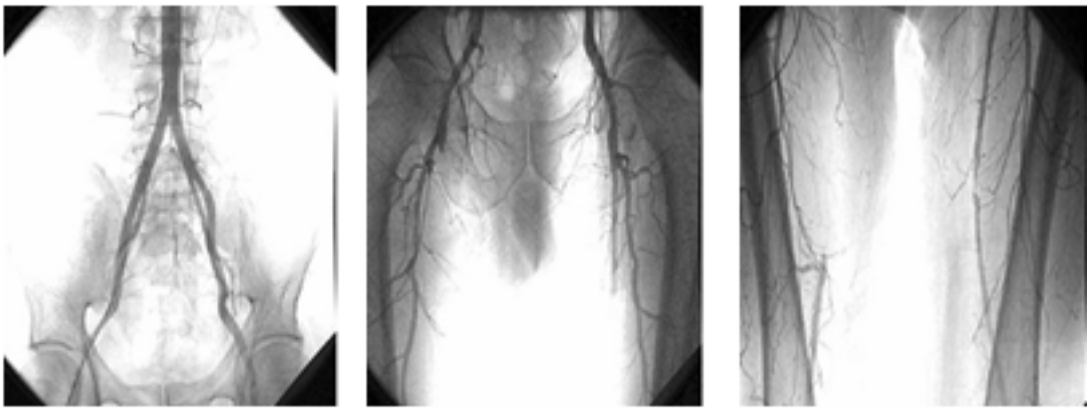
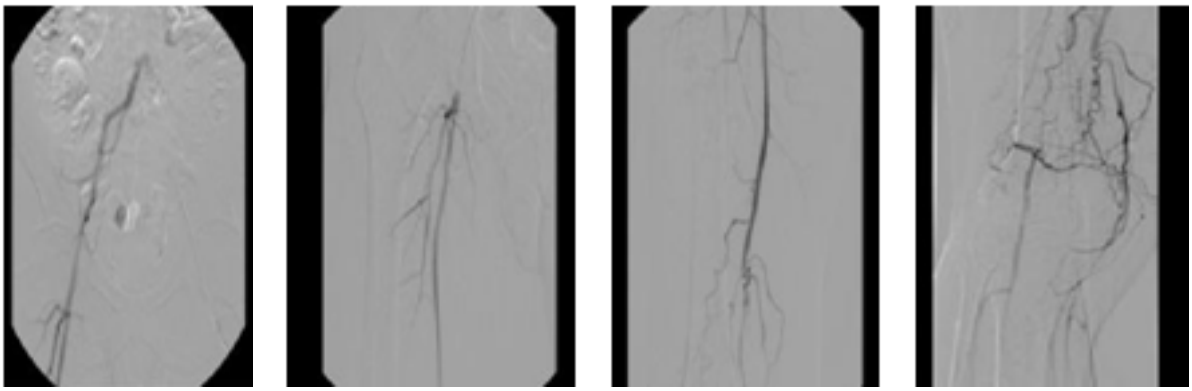
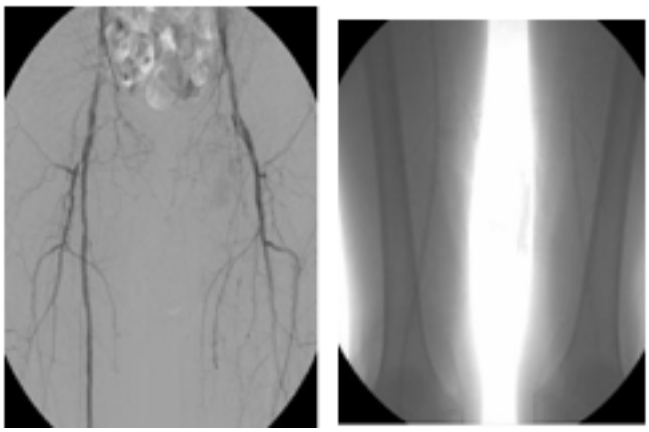
TASC A- Lt (Small segment stenosis of the mid SFA).



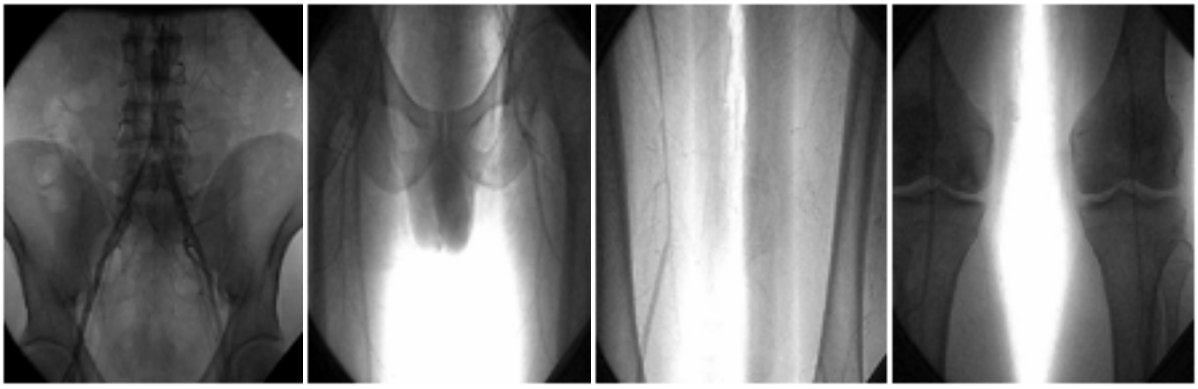
TASC B-(Occlusion > 5cm in the distal SFA extending into the P1 segment).



TASC C- Lt (Occlusion of SFA >15cm and <20cm).



TASC D- Lt (Occlusion of SFA >20cm).



- **Inclusion criteria** :

  Patients who underwent infrainguinal bypass surgery for CLI and incapicitating claudication

- **Exclusion criteria** :

  - Infrainguinal bypass done as part of sequential bypass with proximal outflow disease correction
  - Patients not undergone any earlier infrainguinal vascular procedures
  - Acute limb ischemia
  - Trauma

- **Factors studied** :

  - Age and sex distribution
  - Etiology –Atherosclerosis / Thromboangiitis obliterans / Arteritis / Smoking
  - Clinical presentation – critical limb ischemia /extent of tissue loss / severity of claudication / Pre and post operative ABI /clinical level of occlusion CT angiogram details
  - Co morbid factors – diseases such as Diabetes Mellitus / Systemic Hypertension / Coronary Artery Disease / CVA /

history of tobacco abuse/ CKD/CRP levels/ Hyperlipedimia /hypothyroid etc

- Operative details— level of revascularization, conduit used, post operative vessel status

- Graft patency

- Clinical categoric improvement and limb Salvage

- **Etiology** :

Patients were categorized according to the etiological factors as

- *Atherosclerotic obliterans*

Inflammatory arteritis,vasospastic disorders and medial calcification are some of arterial diseases of the lower limbs . However, by far the commonest cause of peripheral arterial disease is Atherosclerosis consisting of slow accumulation of lipids and fibrosis in the arterial intima.

- *Thrombo angitis oblierans - Shionoya's criteria*
    - Less than 50 years age at onset
    - Smoking
    - Infrapopliteal lesion
    - Upper limb lesion
    - Phlebitis migrans
    - Absence of ASO risk factors

- *Arteritis* - raised CRP
- *Hypercoagulable* state

- **Treatment** of Chroniic Critical Limb Ischemia

1. Endovascular intervention: The optimum lesion for PTA (Percutaneous transluminal angioplasty) are short stenosis or occlusions of the iliac and the proximal SFA with good run off.

2. Surgery: For long occlusion and infrainguinal lesion endovascular treatment is more complex and if intervention is required then bypass surgery gives better results

3. Non-interventional management: In about 10% of patients ,it will be technically impossible to revascularise th limb.Several pharmacological agents have been tried and the most promising are prostanoids, particularly prostacyclin.Iloprost ,a stable prostacyclin analogue , has reduced the amputation and death.In some patients the limb survives , but pain remains a problem.If simple analgesia is inadequate then Lumbar sympathectomy either chemical or surgical may be helpful.In this study only patients who underwent bypass surgery were enrolled.

- **Indication for bypass** :

Critical limb ischemia

Patients develop severe claudication symptoms after a few steps and walking is impossible even in the absence of gangrene, ulceration / tissue loss, or rest pain.

Incapacitating claudication

European Consensus Document defines CLI as persistent, recurring ischemic pain requiring opiate analgesia for at least 2 weeks and ankle systolic pressure lower than 50 mmHg and or toe systolic pressure lower than 30 mmHg; or ulceration or gangrene of the foot or toes.

Critical limb ischemia is often fatal if untreated, but even after arterial reconstruction or amputation, 40-75% of patients will die within 5 years of presentation mainly due to cardiac problems.

- **Anatomical Level of Revascularization:**

  Categorized according to the level of occlusion and analyzed for the type of revascularization as follows

  - Femoral- Proximal Popliteal Artery
  - Femoral- Distal Popliteal Artery
  - Femoral- Anterior Tibial Artery
  - Femoral- posterior Tibial Artery
  - Femoral- TP Trunk

Compliance mismatch and to reduce shear stress while performing distal bypass anastomosis by creating anastomotic vein cuff or vein patch (Millers cuff, Lintons

patch, Taylors patch and St Marys Boot) in case of prosthetic graft placement. Topical papavarine and intraoperative Dextran infusion 15 ml/hour, continued in postoperative period for 48 hours if cardiac function is good.

- **Graft characteristics** :

  Autologous vein

  Synthetic graft

  Composite graft

- **Outcome reporting :**

  Various outcomes can be used in the measurement after treatment including graft patency, limb salvage, clinical status, and quality of life.

  Following revascularization a sustained rise of > 0.15 of ABI was taken to indicate a successful bypass (Normal ABI is > 0.97) and the clinical change is gauged after revascularization.

Scale for gauging change in clinical status

+3	Markedly improved	No ischemic symptoms, and any foot lesions completely healed; ABI essentially" normalized" (increased to more than 0.90)
+2	Moderately improved	No open foot lesions; still symptomatic but only with exercise and improved by at least one category; ABI not normalized but increased by more than 0.10
+1	Minimally improved	Greater than 0.10 increase in ABI" but no categorical improvement or vice versa (i.e., upward categorical shift without an increase in ABI of more than 0.10)
0	No change:	No categorical shift and less than 0.10 change in ABI
-1	Mildly worse	No categorical shift but ABI decreased more than 0.10, or downward categorical shift with ABI decrease less than 0.10
-2	Moderately worse	One category worse or unexpected minor amputation
-3	Markedly worse	More than one category worse or unexpected major amputations

The above said method of reporting system was followed in this study to follow uniformity in the reporting standard. In this method of reporting a combination of the clinical method and segmental pressure index were used to assess the patient's clinical improvement or deterioration. This categorizing of the result is useful in grading of the outcome in the same way for all the patients and useful in assessing clinical success in the follow up period.

Post operative details --

- Category improvement
- Rest pain relief
- Ulcer healing
- Improvement Ankle brachial index
- Wound complications
- Further interventions, if any

- **Graft surveillance methods**

Graft surveillance was done by symptomatic analysis of rest pain status, claudication status, palpable popliteal pulse and distal pulses, ABI determination, Shape of doppler waveform in duplex scan and if needed by CT Angiogram

Clinical examination -- of Rest pain status, Claudication status, Pulse status like palpable femoral, popliteal and distal pulses examination with

handheld Doppler and Duplex scan for failing signals and with post operative ABI.

ABI determination -- using hand held continuous wave Doppler

ABI is calculated by measuring highest systolic ankle pressure divided by the brachial systolic pressure. Brachial pressure is taken as standardization because it corresponds well with aortic and femoral pressure. Diastolic pressure does not fall until the stenosis is quite severe and hence systolic pressure is sensitive.

Duplex scan-- is highly sensitive and specific for identifying lesion that threatens the graft patency. Combination of B-Mode real-time anatomic imaging and Doppler spectral wave analysis with measurement of flow and velocity. Duplex scan identifies failing graft which is defined as hemodynamic disturbances without thrombosis. Color flow image rapidly identifies the region with high velocity or disturbed flow. Duplex criteria for normal flow in graft is PSV less than 125cm/sec & velocity ratio of 1:1.4

First duplex scan screening was done at operation theatre if needed, if not prior to discharge from hospital. The pre discharge duplex examination permits identification of bypass which are prone to progress, which if it occurs and is corrected in timely fashion dramatically reduce the incidence of thrombosis within first year of bypass surgery.

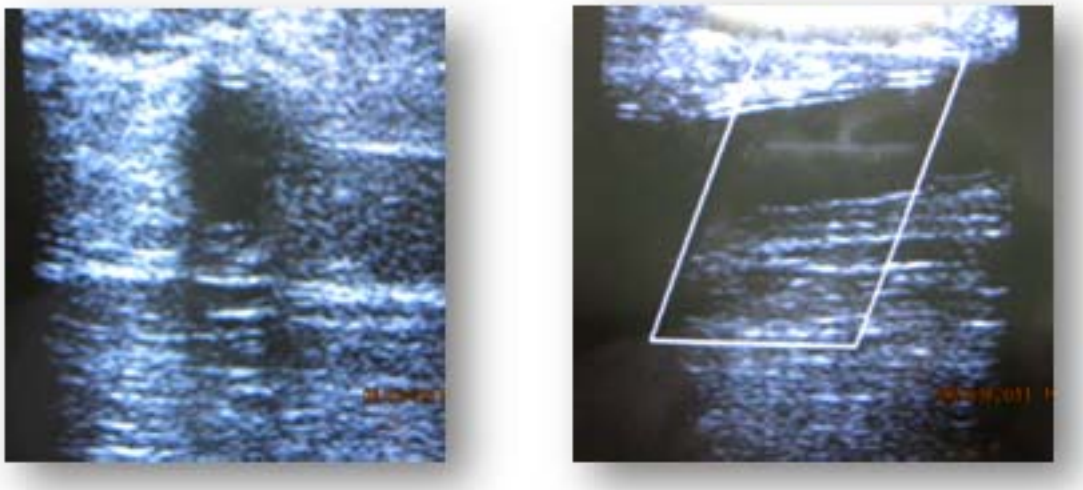
When a graft develops a low flow state, attention should be directed to possible causes a) Loss of inflow b) Outflow impediment c) Critical graft stenosis creating an impediment of flow.

Shape of Doppler waveform is important in early postoperative period, as grafts have a continuous antegrade flow during the cardiac cycle. This is thought to be secondary to the chronic vasodilatation which is caused by the baseline peripheral arterial lesions that have bypassed. As vascular tone is regained over time the waveform becomes triphasic .Conversion from a triphasic to a monophasic waveform with decreased PSV is suggestive of a remote occlusive lesion. A pre occlusive staccato signal portends a poor prognosis and is indicative of high grade stenosis in the distal graft.

Flow patterns in duplex scanning-- Forward flow due to stenosis and low peripheral resistance (capiilaries open which is normal only after exercise and not in stenosis / obstruction) is known as*Monophasic* flow. Distal to severe arterial obstruction due to slowed systolic acceleration & increased diastolic flow is known as *Dampened* flow. *Highest end diastolic velocity* means diameter reduction (DR) will be normal till 50% .It will be elevated in 50-70 % DR to >100cm/s

CT Angiogram -- Site of occlusion, distal reformation, Angiographic runoff score and to delineate future planning like revision procedure if needed

All patients were followed at 1st month from the day of surgery and at end of 12th month. Patients who had a decrease in the ABI of 0.15 as compared to the discharge values or CDFI evidence of PSV>180cm/ sec or <30cm/ sec will be considered as have failing graft and were taken up for angiography if it is necessary for post operative evaluation



Showing grey scale appearance of the graft.

CDFI of a patent graft and its flow pattern.

- **Graft patency** rates were calculated for 1, 3, 6, and 12 months.

1. A graft was considered to have *primary patency* as long as the patency was uninterrupted (was defined as the period between the initial bypass operations till the graft occlusion).

2. *Primary assisted patency* was defined as any interventions preserving the patency of the failing graft (patent graft with PSV > 180cm/s or < 30cm/s, ABI < 0.15 from the previous values).

3. When the graft patency was restored successfully (after graft occlusion), it was recorded as *secondary patency*. Secondary patency lasted until the graft was permanently occluded.

   Graft patency rates were calculated with respect to the run off status and also with respect to the graft size and smoking status of the patients. Secondary patency is restored after occlusion by any of the following procedures

   - Fogarty and adherent clot catheter were used for-- graft thrombectomy
   - Short segmental stenosis <1.5cm-- Balloon
   - Angioplasty.
   - Long stenosis >4cm--Interposistion graft
   - Short focal stenosis (<4cm)-- Patch plasty
   - Thrombolysis-- using systemic or regional Heparin
   - Long segment stenosis that involving anastomotic site --Jump graft
   - Transposition graft --connecting the bypass to different vessel target
   - For diffuse intimal hyperplasia with narrowed caliber --New graft

- **Pre Operative Evaluation**

Duplex Scan - The Duplex scan is specific for identifying lesion that threatens the graft patency and hemodynamic disturbances in the graft. Color flow image rapidly identifies the region with high velocity or disturbed flow.

Hand Doppler- continues wave Doppler

Anesthetic assessment was done and the risk categorization was done as per *Goldman risk* categorization method, taking into the investigation of the individual patient. Most of the patient underwent surgery under regional anesthesia with the intent to have post operative pain relieving by continuous epidural anesthesia. These patients also had spinal anesthesia along with epidural anesthesia.

- **Operative Technique**

Patients were given third generation cephalosporins (for gram + ve bacteria) and renal adjusted does of amino glycosides (for gram – ve bacteria) and metronidazole in selected patients 30 minutes before the operation to prevent surgical site infection. Patients were subjected to femoro-popliteal or femoro-tibial bypass grafting (in addition to the adjuvant inflow and out flow procedures as required) with GA, Spinal, epidural anesthesia. RGSV or prosthetic graft (e PTFE) of suitable size was used.

After exposing the vessels, all patients were given IV heparin (100 IU/ Kg body weight and not more than 5000 IU) and was repeated 1000 IU every hourly if the duration of the surgery was more than 1 hour. During the surgery, popliteal artery

was first exposed by medial approach and its patency was confirmed by getting good back bleed. If required endarterectomy of the popliteal artery was done to establish good back bleed. Routine insertion of Fogarty catheter into the distal vessels to assess the patency was not done. Heparin saline was then infused into the distal vessels by an infant feeding tube kept inside the popliteal artery. Then femoral artery was exposed by vertical groin incision and good antegrade flow was confirmed. Distal AV fistula to enhance the graft patency was not done in any of the cases. None of the patients required protamine for reversal of the effect of heparin. Postoperatively all patients were given plain heparin or LMWH for 5 days & Tab. Aspirin 150mg OD & Tab. Clopidogrel 75mg OD was started once the drains were removed and continued till lifelong. Along with these drugs, Tab. Atorvastatin 20mg HS was given to all patients and other drugs as per their co-morbidities.

- **outcome**

Limb salvaged / major amputation/ minor amputation

- **discharge status**

- **followup**- 1,3,6, and 12 months

The initial evaluation of the patients starts prior to discharge or within one month after implantation, followed by on 3 months,6 months and 12 months .

All the patients were recommended aspirin or clopidogrel and, statin in ASO groups, postoperatively to decrease graft occlusion as well as for its cardio protective effects and in high risk group, if needed, long term anticoagulation like Tab .Acitrom was advised.

- **Statistical analysis** was done to compare mainly the graft patency rates with respect to the run off status and also with respect to the graft type (RSV or PTFE) , smoking status etc as they independent predictors of the graft patency.

P value was calculated by using Chi- Square test to establish the statistical significance. P value of < 0.05 was considered as statistically significant .

REVIEW OF LITERATURE

The peripheral arterial occlusive disease of femoro popliteal segment is one of the commonest arterial lesions of the lower extremity, especially in patients over 60 (Text book of vascular & endovascular surgery By Jonathan D Beard) [25]. The clinical manifestations of arterial lesions vary with their location and extent, as well as the degree of associated vascular lesions. They are divided in 3 major groups of increasing severity. (Intermittent claudication, Ischemic Rest pain and gangrene) Graft thrombosis in the early postoperative period represents a failure for both patient and surgeon. The causes for the graft failure involve both patient factors and technical factors. It is believed technical errors at the time of operation account for early failures and some cases of late failure in long follow up, and there is general agreement that technical factors account at least for early failures. The patency rates have been related to clinical severity of ischemia, run-off, diabetes and diameter of vein.

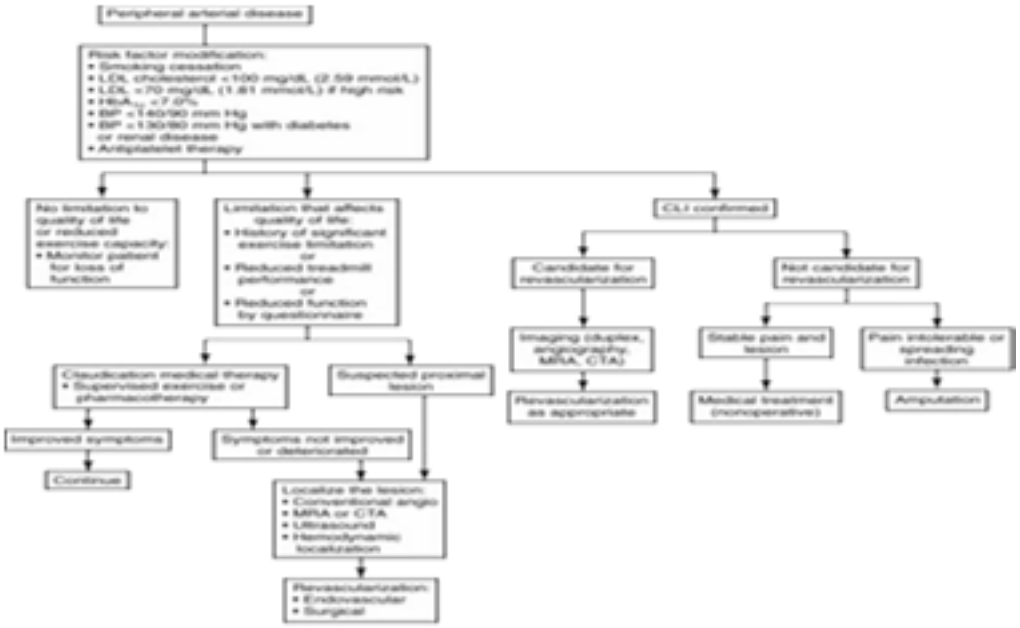
Introduction of thrombo-endarterectomy by J.CID.DOS SANTOS in 1947 and by pan grafting technique by Kunlin in 1940 marked the beginnings of the direct revascularization methods of the lower extremity (Vascular surgery principles & techniques- By Haimovici) [26]. Evaluation of these operations is centered on the early and long-term results as they relate to a number of factors like selection of patients with regard to functional improvements or limit salvage, type of reconstruction, the grafting material, associated diabetes mellitus, influence the results of lower extremity arterial reconstruction.

The ACC/AHA guidelines suggest that the risk of major limb amputation for a patient with intermittent claudication is approximately 1% per year, whereas the risk of cardiac death is approximately 3% to 5% per year [29] *(Am J Surg* 1976) . Treatment strategies have therefore

stressed cardiovascular risk factor modification and medical therapy as the best initial treatment for patients with PAD symptoms limited to intermittent claudication. *Revascularization* is recommended only in cases of severe claudication, and only after medical therapy has failed.

Pharmacotherapy for CLI has failed to yield any breakthrough therapy. The routine use of modern wound care methods such as negative-pressure wound therapy, intense debridement, and antibiotic therapy, prostanoids, vasodilators, antiplatelet agents, and even hyperbaric oxygen for the treatment of ischemic ulcers remains of unproven benefit [30]. Thus revascularization is an essential component in the relief of CLI.

In January 2000, the Trans-Atlantic Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC) published a document authored by a working group of representatives from 14 surgical vascular, cardiovascular, and radiologic societies [28].-An upgraded document (TASC II) was published in January 2007. [27]. [28] (J Vasc Surg. 2007; 45-Suppl)



Management of lower extremity peripheral arterial disease according to TASC II [28]

Endovascular Treatment versus Open Surgery:

Diffuse, extensive PAD causing CLI in femoropoplital locations are best treated by surgical bypass according to TASC. Open surgery is usually associated with higher perioperative morbidity and longer hospitalization (*Eur J Vasc Endovasc Surg)* 2005 [(31)]. Expensive and tedious long-term postoperative graft surveillance is necessary to maintain a patent infrainguinal bypass suggest that such surveillance is economically justified by preventing graft occlusion and late amputation. A re-intervention rate of 20% to 30% to treat failing grafts due to intrinsic graft stenosis is usually necessary to maintain the increased durability attributed to open surgery. Those who favor interventional treatment cite the low morbidity and mortality associated with a procedure that is usually performed on an outpatient basis [(32)]. Though proponents acknowledge the limited reconstruction patency rates associated with interventional treatment, especially for the high-risk lesions often encountered in CLI, they argue that restenosis rarely jeopardizes subsequent surgery [(32)] *(Eur J Vasc Endovasc Surg)* 2003).

Choice of the conduit:

Kunlin's first description of the successful use of autogenous vein to bypass femoro popliteal arteriosclerosis obliterans, there is near universal agreement that autogenous vein is the best conduit for infrainguinal bypass at all levels(*J Vasc Surg* 1990; 11:193-205) [(33)]. The great saphenous vein (GSV) is the most readily available and durable conduit. Ipsilateral small saphenous vein, the contralateral great and small saphenous veins, and the upper extremity veins are the alternatives in the order of preference. Assessment of vein availability and quality is critical and should be carried out before embarking on the operation. Cryopreserved vein grafts are expensive and have not performed well in clinical practice [(34)]; they may serve a niche role

when revascularization is required following the removal of an infected bypass graft and autogenous vein is unavailable to create a new bypass through clean tissue planes(*J Vasc Surg*) [(34)].

One of the most prosthetic infrainguinal bypass conduits is ePTFE. Studies suggest that biologically active heparin has been successfully covalently bonded to ePTFE without causing systemic anticoagulative effects [(35)] has improved prosthetic graft patency in humans*(J Vasc Surg* 2006).

For bypasses that insert below the knee, the addition of a vein cuff confers a significant patency advantage (52% patency at 2 years for PTFE with vein cuff versus 29% for PTFE with no cuff) and also improves limb salvage (84% versus 62%; $P < .03$) [(20)].

Out comes of femoro popliteal bypass:

Graft patency, limb salvage, and mortality are objective endpoints. Subjective endpoints are functional outcome and quality of life. Nicoloff and coworkers emphasized that an ideal outcome—defined by the expectations of a patent graft, healed wound, no need for reoperation, independent living status, and continued ambulation. Only a small fraction of patients in their report (14.3%) met these basic criteria for success. Abou-Zamzam and colleagues identified preoperative independence and ambulation as the best predictors of postoperative independence and continued ambulation [(63)]. These data emphasize the severity of underlying co-morbidities in CLI patients and the difficulties encountered in obtaining functional limb salvage. Prospective trials (PREVENT III [Prevention of Recurrent Venous Thromboembolism] and BASIL [Bypass versus Angioplasty in Severe Ischemia of the Leg]), support regarding the effectiveness of leg bypass in relieving ischemic symptoms and improving quality of life (QoL) in properly selected

patients. Patients with true CLI have a markedly reduced QoL compared with a normal control population and their QoL is markedly improved by successful bypass [37]. It is also becoming evident, especially in CLI patients, that ongoing graft patency, at least for the first 1 to 2 years, is critical to the maintenance of this QoL improvement [38].

Female gender is frequently cited as a factor that negatively influences the outcome of open or endovascular reconstruction. One reason is the inflow and outflow vessels, are typically smaller in women.Endovascular treatment(ET) for infrainguinal disease, preliminary results suggest a trend toward improved outcomes following the treatment of femoro popliteal lesions compared with infrapopliteal lesions(*Ann Surg* 2007) [39]. ET of stenotic lesions yields better immediate and long-term outcomes than does the treatment of occluded lesions [40].

As per a national survey by the Vascular Surgical Society of Great Britain and Ireland, around 70% of patients with critical limb ischemia were offered some form of revascularization procedure, with a 75% chance of limb salvage. The overall amputation rate was 21.5% and mortality rate was 13.5% [43]. In the NHANES study the following risk factors (and odds ratios) were significantly associated with PAD: black race/ ethnicity (OR- 2.83), current smoking status (OR- 4.46), diabetes (OR- 2.71), hypertension (OR- 1.75), hypercholesterolemia (OR- 1.68) and poor kidney function (OR- 2), elevated fibrinogen and C reactive protein levels [44]. There is clear evidence from several studies that increasing age is associated with an increased risk of PAD in both men and women [44]. Cigarette smoking is associated with excess premature deaths from CVA, respiratory and cancer related diseases [46]. Smoking is undoubtedly the most important modifiable risk factor for PAD. Smokers are more likely to progress to critical limb ischemia and more likely to require an amputation or vascular intervention. Smoking increases the overall mortality rate among claudicants by a factor of 1.5- 3.0 [45].

The Framingham and other related studies have provided good evidence that hypertension is a powerful predisposing factor for development of PAD. Up to 5% of hypertensive patients have been reported to have clinical evidence of PAD at presentation, with a marked age related increase in hypertension associated PAD [47]. In the Rotterdam Study investigating determinants of PAD, after multivariate analysis each 10mmHg increase in systolic BP conferred an increased risk of PAD (OR 1.3, 95% CI 1.2- 1.5) [48]. Effective antihypertensive therapy is likely to ameliorate the progression of PAD as well as reducing the mortality from stroke and coronary artery disease. The REACH (The Reduction of Atherothrombosis for Continued Health) registry confirmed that patients with atherosclerotic disease affecting several arterial territories had proportionately higher risk of a major CV event [48].

A meta-analysis by the Antiplatelet Trialists' Collaboration showed that antiplatelet therapy, mainly with low-dose aspirin, reduced the risk of non-fatal MI, non-fatal stroke and vascular death in high risk patients, including those with intermittent claudication [49]. The CHARISMA trial was performed to assess the effects of dual antiplatelet therapy (aspirin + clopidogrel) in patients with more stable atherosclerotic disease [50].

Endovascular Treatment and Recent Advances

Endovascular treatment (ET) is increasingly the first option for treating infrainguinal peripheral arterial disease (PAD). Percutaneous transluminal angioplasty (PTA) with adjunctive stenting is a well-validated and increasingly used technology, and it is the technique most frequently employed for infrainguinal ET. An alternative to transluminal angioplasty is subintimal angioplasty (SIA), also referred to as percutaneous intentional extraluminal revascularization. SIA is used to cross occluded vascular lesions and recanalization is performed by intentionally

exiting the vascular lumen, entering the subintimal plane and then reentering the vascular lumen distal to the lesion. Stenting is an adjunctive procedure used either routinely or selectively for the treatment of complex lesions or persistent stenosis or to correct intraprocedural complications. The new TASC femoro popliteal criteria reflect the fact that increasingly complex disease can be managed using endovascular techniques. TASC type A lesions are suitable candidates for ET; TASC type D lesions necessitate surgery, owing to ET's prohibitive failure rate; and TASC types B and C lesions can be treated using either endovascular or surgical revascularization, depending on the clinical scenario.

Bypass versus Angioplasty in Severe Ischemia of the Leg (BASIL) trial was a multicenter randomized controlled trial that assigned 452 patients to a surgery-first or angioplasty-first approach [(41)]. The primary endpoint was amputation-free survival, and at 6 months' follow-up, there was no significant difference in amputation-free survival between the two groups. Health-related quality of life, as measured by the EuroQol 5-D and Short Form 36, did not differ significantly between the two groups. The minimally invasive nature of PTA, improvements in technology, and growing operator experience have increased the aggressiveness with which complex infrainguinal lesions are approached using ET.

The modulation of growth factors to stimulate angiogenesis is an area of focus in the treatment of lower extremity PAD, particularly in patients who are not candidates for surgical or interventional techniques. Therapeutic angiogenesis is defined as the growth of new blood vessels from preexisting blood vessels to treat ischemic disease. The putative concept by which angiogenesis improves limb perfusion is the growth of new blood vessels and possible direct stimulation of wound healing by growth factors.

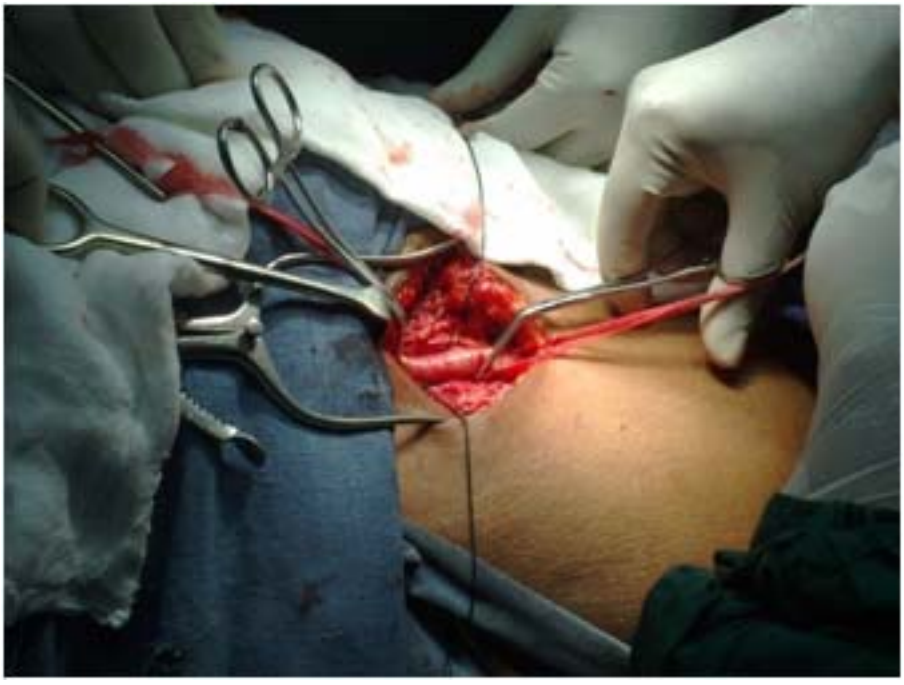
The Therapeutic Angiogenesis with Recombinant Fibroblast Growth Factor-2 for Intermittent Claudication (TRAFFIC) study was the first randomized clinical trial to show a positive effect of growth factor therapy in limb ischemia [51]. The Therapeutic Angiogenesis Leg Ischemia Study for the Management of Arteriopathy and Nonhealing Ulcer (TALISMAN) trial demonstrated that intramuscular injection of FGF-1 resulted in a twofold decrease in major amputation compared with placebo [52].

Stem cell therapy is another technique to induce therapeutic angiogenesis. This technique has used bone marrow mononuclear cells or endothelial progenitor cells obtained from bone marrow harvest or, from circulating peripheral blood stem cells. Endothelial progenitor cells can be identified by cell sorting for CD34-positive, VEGF receptor-2–positive cells. Once concentrated, the cells can be injected into the ischemic limb to induce angiogenesis. Tateishi- Yuyama and coworkers, in a randomized prospective trial, showed that injection of bone marrow–derived mononuclear cell injections resulted in a significant increase in ABI and $tcPO_2$ compared with controls [53].

Multiple reports have clearly demonstrated improvements in pain free ambulation and overall walking performance with structured exercise training [54]. Data from more than 20 randomized trials have confirmed that exercise therapy is the best initial treatment of intermittent claudication [54]. Although exercise therapy appears to be easy to implement, effectiveness is often limited by poor patient compliance. Effective exercise training is not possible in up to 34% of patients because of co-morbid medical conditions and an additional 30% of patients simply refuse to participate in exercise training [55].

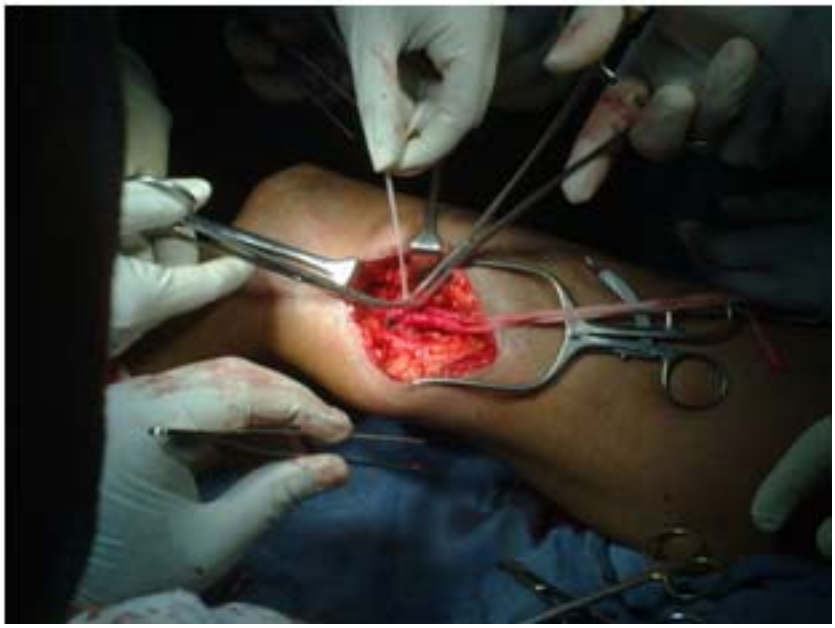
New TASC guidelines are set to recommend an endovascular first strategy even for TASC D lesions. As per the European perspective of TASC managements 2011 for femoro popliteal lesions, revascularization strategies should begin with endovascular approaches in TASC A, B, C and D lesions. Surgical revascularization should be reserved for endovascular failures, occlusion of profunda femoris artery (PFA), severe disease of CFA and PFA and occlusion of popliteal artery with concomitant infra popliteal disease. However TASC II b remains unpublished as vascular surgical societies have so far failed to endorse these recommendations.

CT Angiogram of SFA Occulision



Common Femoral Artery exposure for Proximal Anestomosis

Parachuting of PTFE (Proximal Anestomosis)



Exposure of Proximal Popliteal Artery for Distal Anestomosis

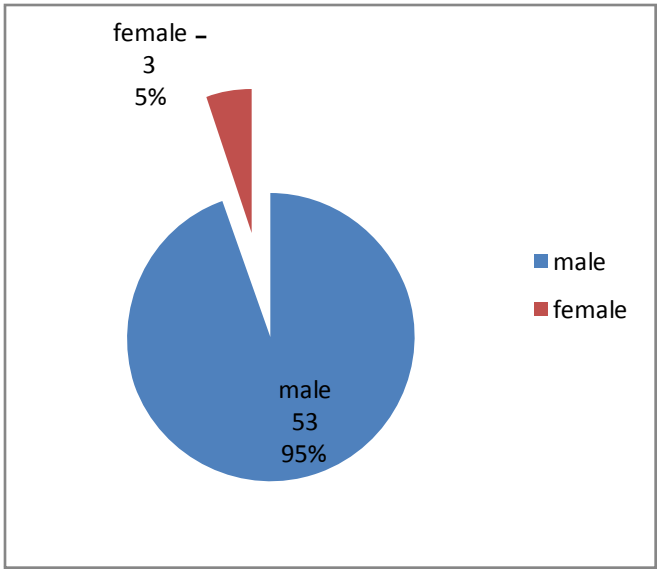
Distal Anestomosis of PTFE to Popliteal Artery

OBSERVATION AND RESULTS

Review of prospectively collected data was performed of fifty six patients who underwent peripheral arterial bypass procedures for lower limb ischemia due to various etiology was randomly selected and enrolled in this study, .Among them 53 were males (94.6 %) and 3 females (5.3 %) .

Patients		Frequency	Percent
	Male	53	94.6
	Female	3	5.4
	Total	56	100.0

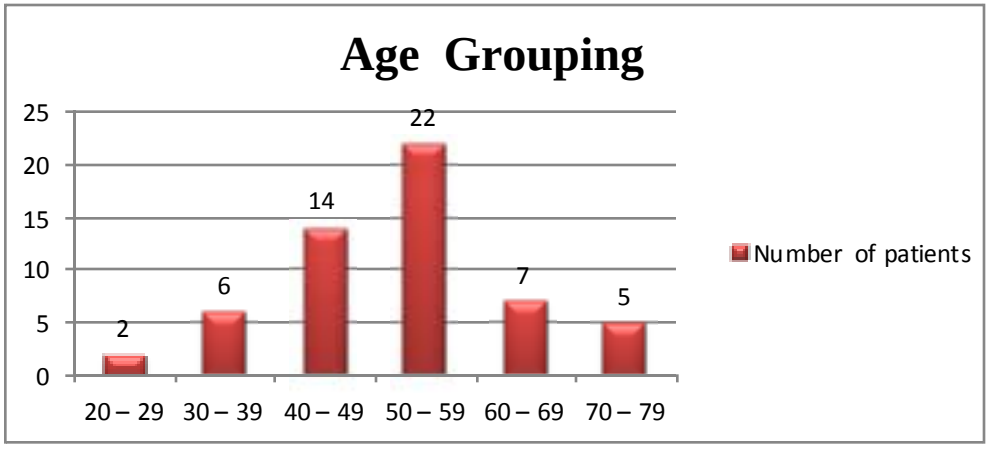
Sex Incidence



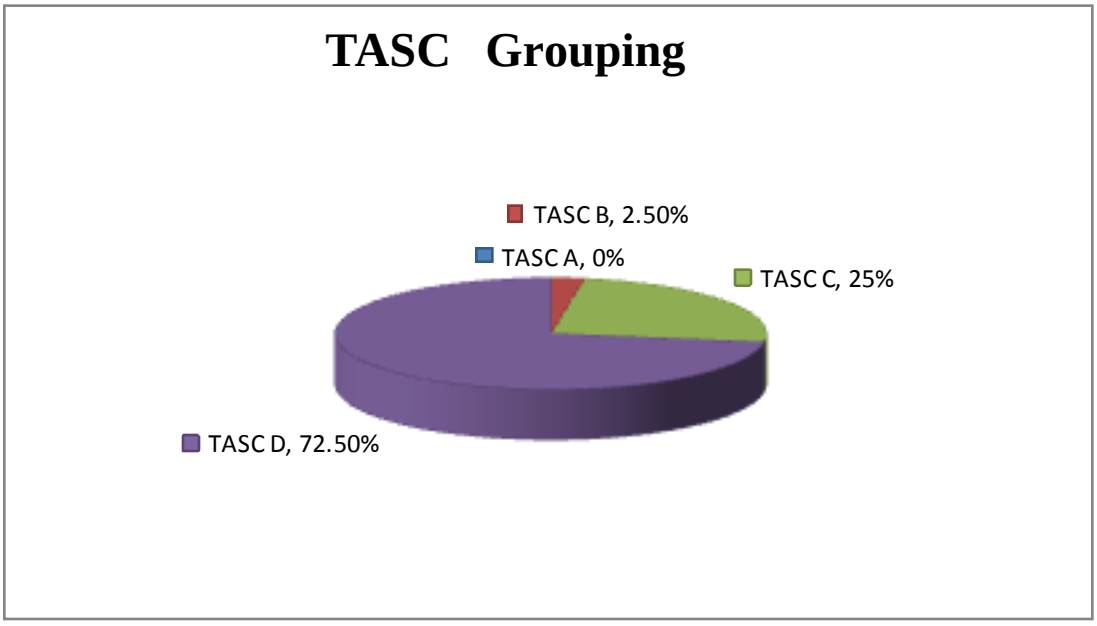
The age varied between 29 yrs to 74 yrs. Most patients were in the age group 40 to 60 years (60.5%). The mean age of patients was 51.57 years

	Minimum	Maximum	**Mean Age**	Std. Deviation
Age in years N =56	26	74	51.57	10.731

Age Group	Number	Percent
20 – 29	2	3.5
30 – 39	06	10.7
40 – 49	14	25
50 – 59	22	39.2
60 – 69	07	12.5
70 – 79	05	8.9



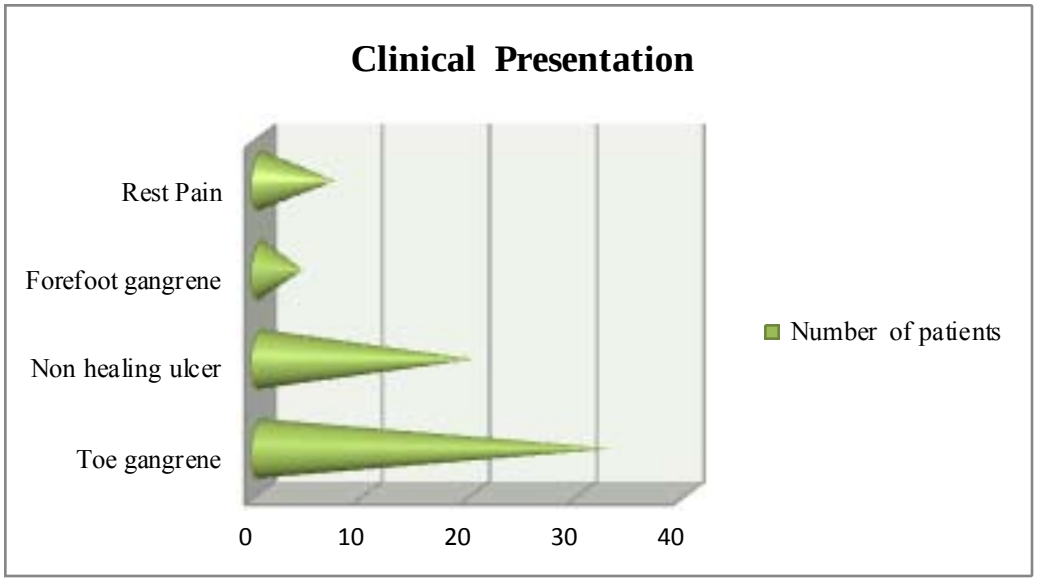
TASC Classification of fem pop disease in this study



TASC D lesion was the most common lesion (72.5%) in this study, followed by 25% in TASC C lesions and 2.5% in TASC B lesions , for which infra inquinal bypass was performed .

Incidence of clinical presentation

Clinical presentation	Number	Percent
Toe gangrene	33	58.9
Non healing ulcer	20	35.7
Forefoot gangrene	04	7.1
Rest Pain	07	12.5

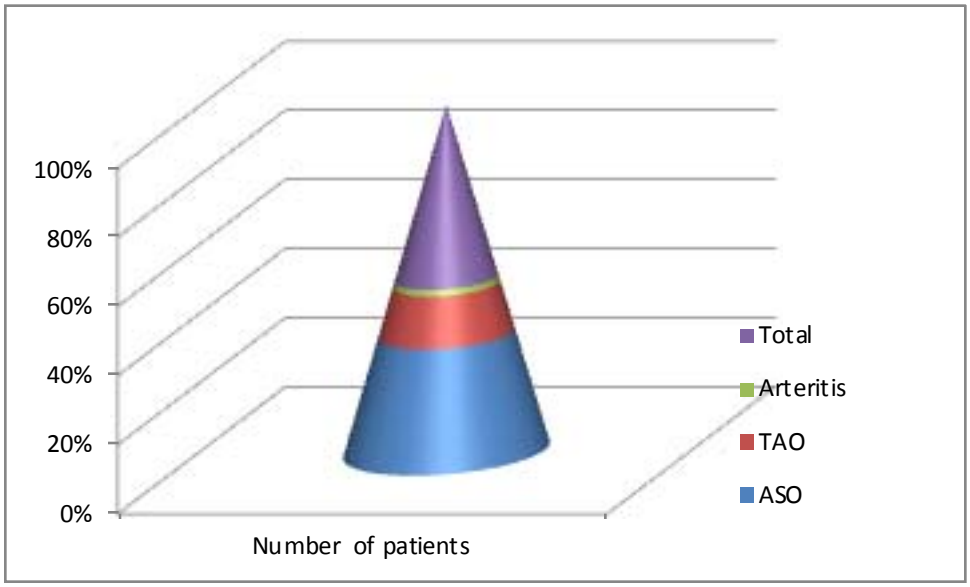


Critical limb ischemia was the most common cause for the surgical intervention. Minor tissue loss in the form of toe gangrene was the most common indication for revascularization (58.9 %). Non healing ulcers(35.7 %),Rest pain(12.5%) and forefoot gangrene formed about (7.1%) of the patients.

Etiology statistics

Etiology	Number	Percent
ASO	38	67.8
TAO	16	28.5
Arteritis	2	3.57
Total	56	100.0

Etiological Presentation

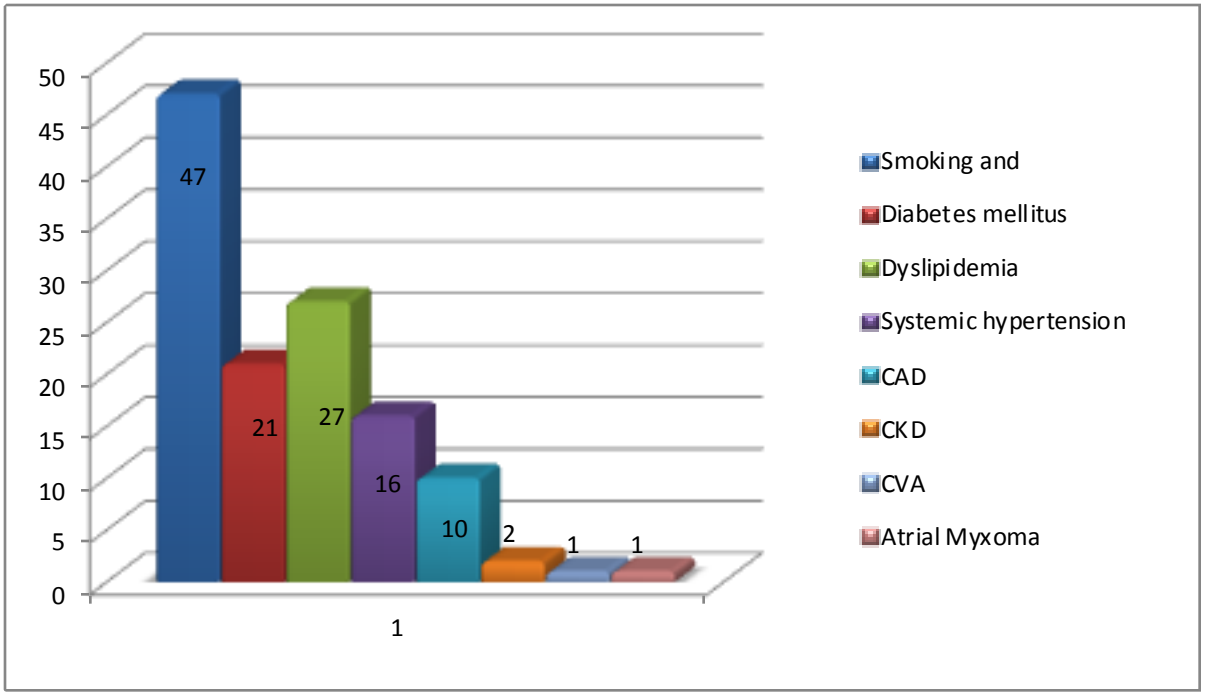


Out of the 56 patients who underwent bypass surgery for chronic limb ischemia, 38(67.8 %) patients were diagnosed to have Atherosclerotic Occlusive Disease, 16(28.5 %) patients were diagnosed to have Thromboangitis Obliterans as per the clinical criteria of Shinoya, and 2(3.5 %) patients were diagnosed to have arteritis forms the major proportion of the patients who underwent revascularization for Critical limb ischemia group.

Risk factors and associated co-morbidities

Risk Factors	Number	Percent
Smoking and smokeless tobacco	47	83.9
Diabetes mellitus	21	37.5
Dyslipidemia	27	48.2
Systemic hypertension	16	28.6
CAD	10	17.9
CKD	2	3.6
CVA	1	1.8
Atrial myxoma	1	1.8

Risk factors



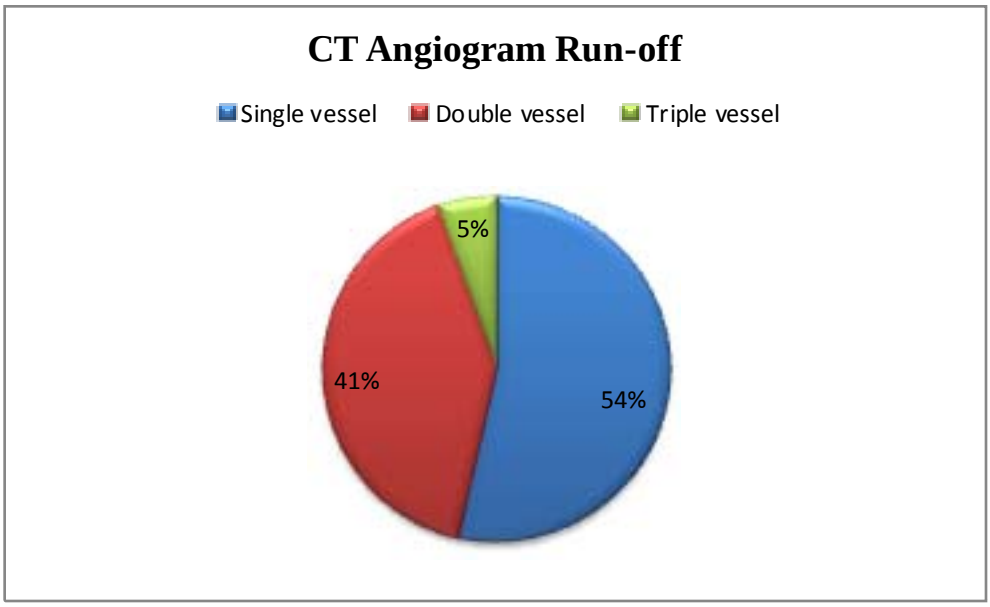
In the study group of 56 patients, very few people had single risk factor but many had multiple risk factors. Among study group (n= 45) 83.9% were smokers, (n= 21) 37.5% were diabetics, (n= 27) 48.2 % were Dyslipidemia, (n= 16) 28.6 % were hypertensive patients, (n= 10) 17.9% were ischemic heart disease patients and remaining patients had other risk factors 1 patients had cerebrovascular accident, 2 patient had chronic renal failure and 1 patient had Atrial Myxoma . Smoking history was present in 83.9% of the patients, which was the single major risk factor in all the patients. 60% of diabetics were not on regular treatment. These diabetics' patients who

had critical limb ischemia were diabetic for a prolonged period. The average period for DM being minimum of 7 years.

Most of them were bare foot walker or were wearing improper foot wear had Ischemic Ulcers and toe Gangrenes. Incidence of CAD, CVA, CKD and diabetes mellitus had very high in outflow collaterals (even though the number was very low); that indirectly indicates the disease burden in these cases . This indirectly explains the poor survival and high complication rates in this group.

CLI patients with respect to Ct Angiogram run off pattern

Ct Angiogram run off	Frequency	Percent
Single vessel	30	53.5
Double vessel	23	41.07
Triple vessel	3	5.3
Total	56	100.0



The incidence of CLI patients with single vessel runoff group are 53.5%, double vessel runoff group are41.07% and three vessels run off group is 5.3%. Even though the three vessels run off group appears to be having high patency rates and no reintervention rates, the p values were insignificant. This could be due to the very low number in three vessels run off group when compared to one and two vessels run off group.

Graft patency in relation to runoff

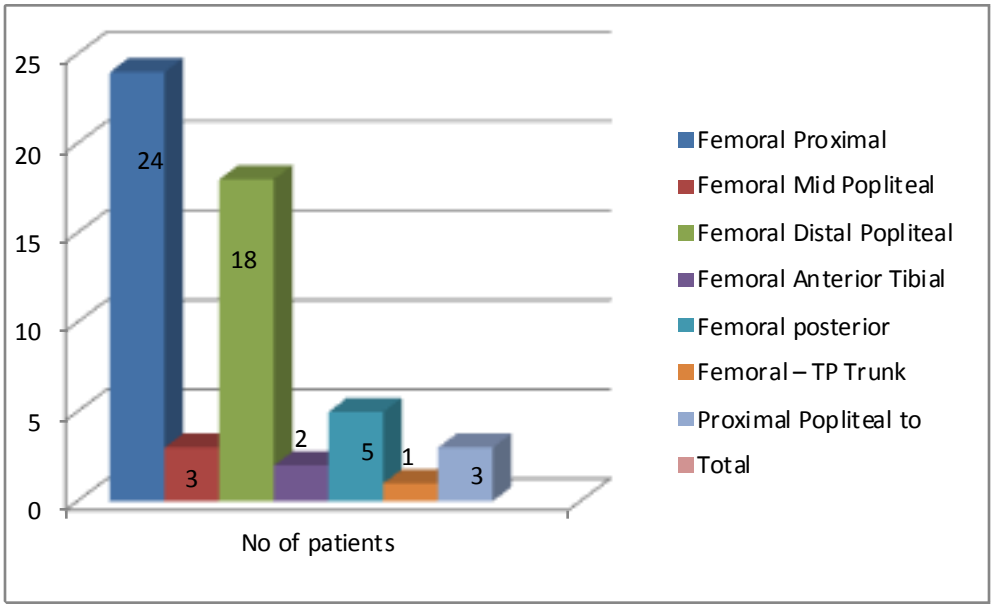
	Numbers	Patent	Occluded	Failing
Single vessel run off	30	19	8	3
Double vessel run off	23	20	1	2
Triple vessel run off	03	2	0	1

Type of Bypass in this series

Femoro popliteal bypass forms the common form of bypass with 43 patients.Among the above group, Femoro proximal popliteal artery bypass was done on 24 patients, Femoro- mid Popliteal Artery surgery on 03 patients and Femoro distal popliteal artery bypass was done on 18 patients. Femoro posterior tibial bypass was performed in (n=05 patients). Femoro anterior tibial bypass was performed in (n=02 patients). Femoro -TP trunk bypass was done for 01 patient while popliteal to various distal arteries bypass was done for 03 patients.

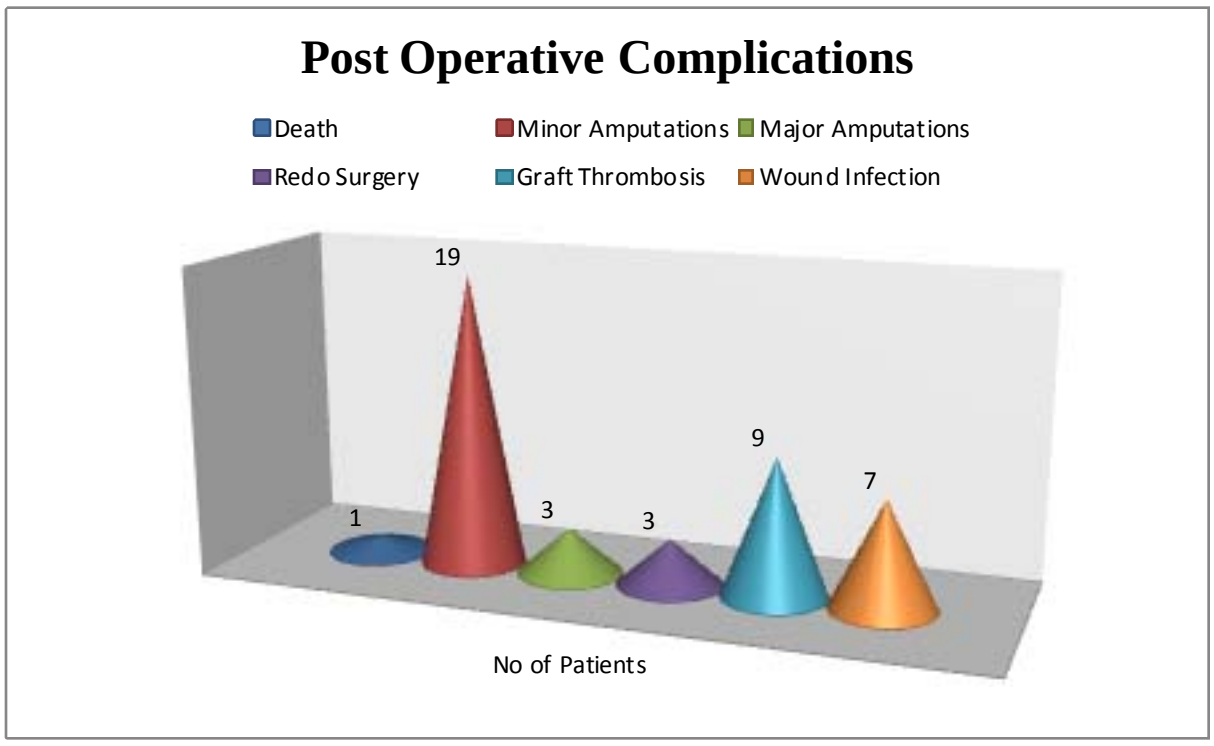
Type of Bypass	Numbers	(%)
Femoral - Proximal Popliteal Artery	24	42.8
Femoral - Mid Popliteal Artery	03	5.3
Femoral - Distal Popliteal Artery	18	32.1
Femoral - Anterior Tibial Artery	02	3.5
Femoral - Posterior Tibial Artery	05	8.9
Femoral - TP Trunk	01	1.7
Proximal Popliteal to Distal PT	03	5.3
Total	56	

Types of Bypass Surgery



Post procedure complications

Complications	Number of the patients	%
Wound infection	7	12.5
Graft thrombosis	9	16.7
Redo surgery	3	5.3
Major amputations	3	5.3
Minor amputations	19	33.92
Death	01	1.7



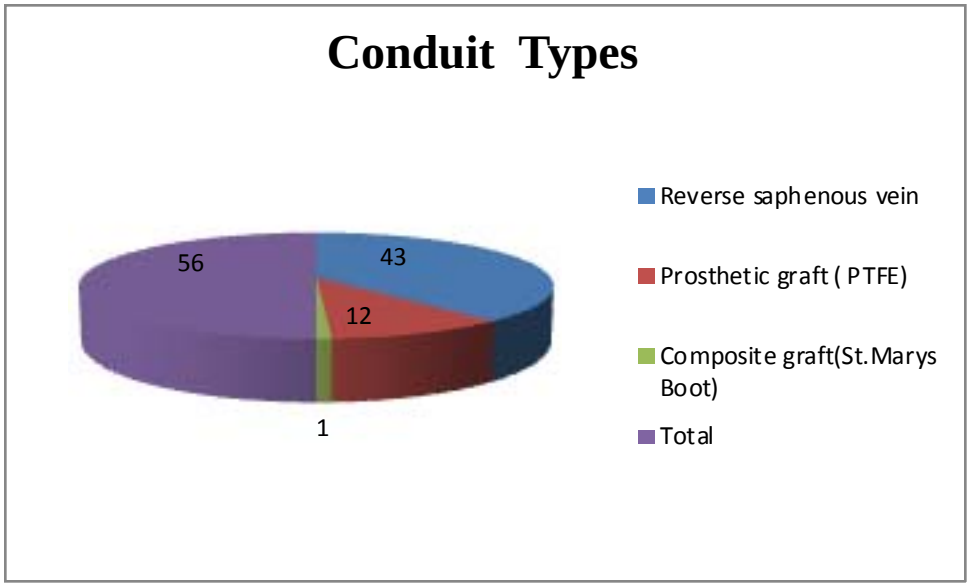
During the post operative follow up period one patient expired in the early postoperative period due to myocardial infarction. Primary patency rate of graft at the end of one year is 80 % (n=44) .Graft thrombosis rate in this study is 16.36% (n=9). Six grafts were identified during their failing stage in the study, out of which 3 patients underwent Redo bypass surgery (PAP 82.1%).Among redo group for 2 , grafts patency restored and their limbs salvaged and 1 graft occluded subsequently and resulted in limb amputation .

Nine grafts were occluded during the follow up period, out of which 2 patients presented with gangrenous stage beyond limb salvageable and underwent major amputation. Remaining graft occluded patients, were asymptomatic and they are under periodical observation.

Patients with wound infection in our series was 12.5% .Primary assisted patency rate in this study is 82.1 %. Limb salvage rate was 94.54%. Failing graft in this study is 10.9% (n=6). Major Amputation rate in this study is (5.3 %)

Types of Conduit

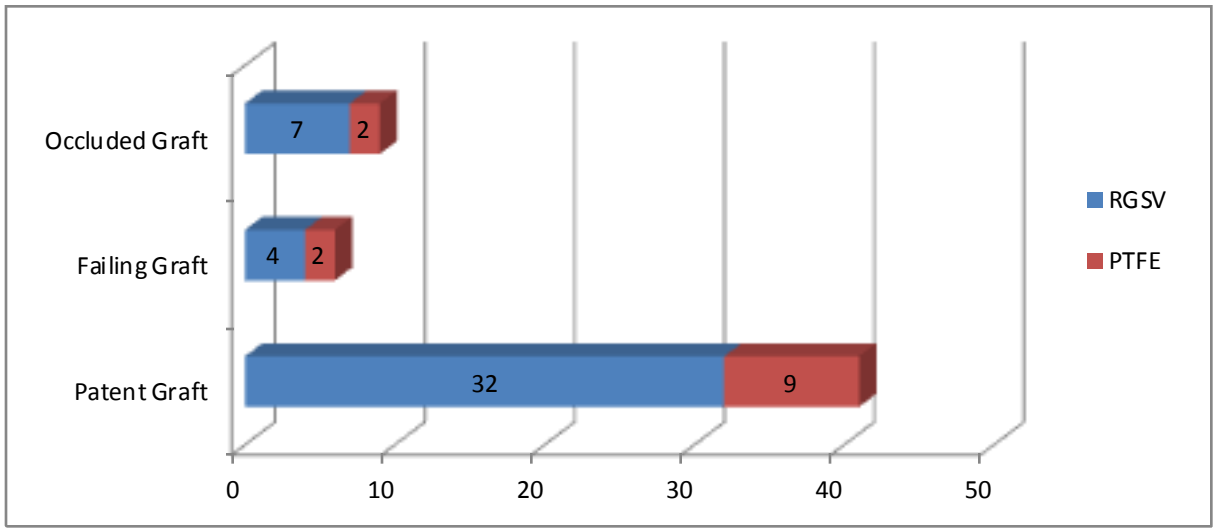
Conduit used	Total number	(%)
Reverse saphenous vein	43	76.7
Composite graft(St.Marys Boot)	01	1.78
Prosthetic graft (PTFE)	12	21.4
Total	56	100



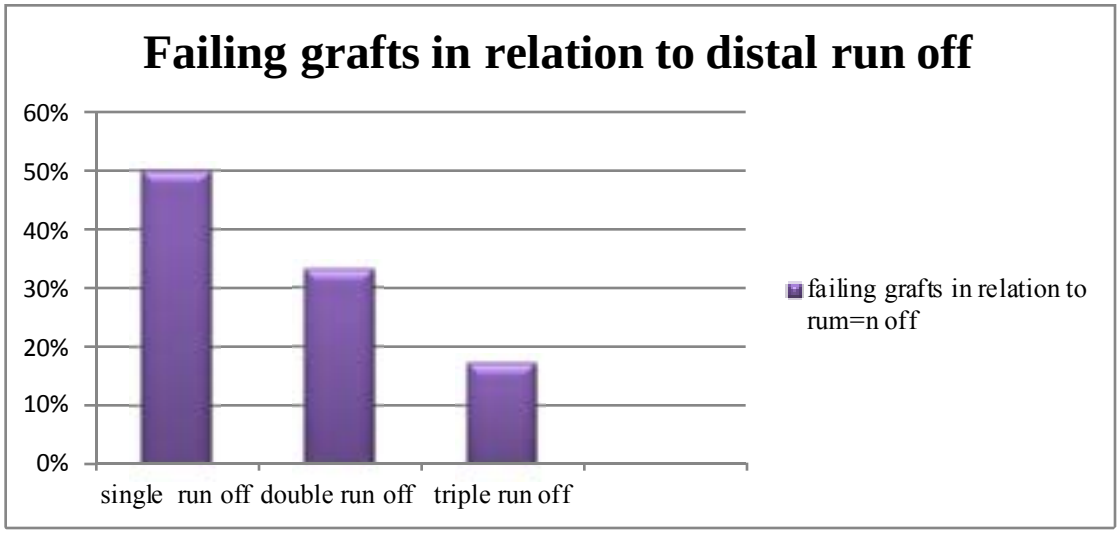
Reversed saphenous vein was the most common conduit, used in 43 patients in our series. Synthetic conduit like PTFE were used in 12 patients for supragenicular limb bypass, and Composite graft(PTFE with St Marys Boot) used in 01 patients to distal popliteal artery in whom the autogenous vein in both upper and lower limbs were of poor quality . Lifelong antiplatelet drugs and oral anticoagulation in selected group of patients (e.g., patient with grafts at high risk of thrombosis such as single vessel run off and in arteritis patients).

Graft patency in relation to Type of Conduit

Conduit	Patent	Failing	Occluded
RGSV (N=43)	**32**	**4** (ASO=4, PT-2,AKB-2,SRO-3,DRO-1)	**7** (ASO=2,TAO=4,Arterits=1)
PTFE (N=13)	**9**	**2** (ASO=2,DRO-1,TRO-1)	**2** (ASO=2)
Total	**41(73.2%)**	**6(10.7%)**	**9(16.07%)**



In our study group infra inguinal arterial bypass surgery, out of total 56 grafts, for 43patients RGSV and 13 (1 = Composite graft) PTFE grafts used. Graft occlusion rate is 16.07% and Graft failing rate is 10.7% in the study group.



The primary patency rate at end our study is 78.6 % (n=44 / 56) where Duplex scan showed normal patent graft during the first visit. Among 44 patent grafts, RGSV were successful in 86.4% and PTFE in 66.7% , which clearly shows Vein graft have good patency rate than synthetic grafts.

Failing grafts detected during study were 6, three of them underwent reintervention surgical procedures. No surgical reintervention performed for occluded grafts they were asymptomatic or not willing for surgery.

Primary assisted patency – Graft Patency

In the post operative study, 9 grafts out of 56 grafts (11.8%) were occluded in follow up period. Six failing identified clinically, out of which 3 patients underwent revision procedure. In revision procedure, 1 got occluded and 2 grafts regained palpable pulses with limb salvage. 1 patient with no pulses subsequently underwent AK amputation. The limb salvage rate in our study was relatively higher (n=53, 94.6%) compared to the graft patency (n=44, 78.6%) including the patients those were observed.

The overall amputation in our study was 5.35 %(n=3), and the mortality rate in this study was 1.7 %.

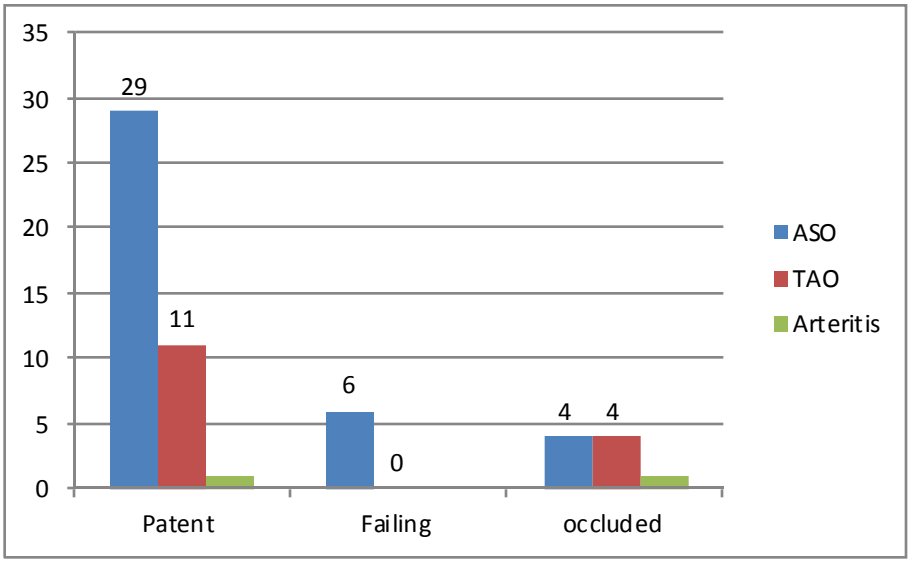
Patency rates with respect to the number of outflow vessels at end of 12 months

Variable	One vessel outflow	Two vessel outflow	Three vessel outflow
Number of Grafts	30(53.5%)	23(41.07%)	03(5.3%)
Primary patency rate	19	20	03
Primary assisted patency (PAP)	1(occluded)	2(patent)	0
Secondary patency rate	N	N	N
Cumulative patency rate	19(33.9%)	22(39.2%)	03(5.3%)

Comparison of graft patency to that of etiology

The graft patency was compared in relation to etiological factors in 56 patients. In atherosclerosis group of 38 grafts used , out them n=29 had patent grafts ,n=4 occluded and n=6 were failing . In thromboangitis obliterans n=11 were patent and n=4 were occuled . In Arteritis group n=1 patent and n=1 occuled . TAO and arteritis had increased risk of graft occlusion during the follow up.

GRAFT	PATENT	FAILING	OCCLUDED
ASO	29	6	4
TAO	11	0	4
Arteritis	1	0	1
Total	41	6	9



Comparison of graft patency to that of bypass surgery(types)

Type of Bypass	NUMBERS	PATENT	FAILING	OCCLUSION
Femoral- Proximal Popliteal Artery	26	18	4	4
Femoral- Distal Popliteal Artery	21	17	0	4
Femoral- Anterior Tibial Artery	03	2	0	1
Femoral- Posterior Tibial Artery	05	3	2	0
Femoral- TP Trunk	01	1	0	0
Total	56	41	6	9

The occurrence of graft stenosis or occlusion is more common in patients who underwent infragenicular bypasses than above knee bypass. This could be due to the increased resistance and low flow state in peripheral arteries compared to that of central arteries. Three patients had undergone AK amputation in the post operative period

Limb salvage with respect to run off status

	One vessel outflow	Two vessel outflow	Three vessel outflow
Number of limbs with CLI	30(53.5%)	23(41.07%)	03(5.3%)
Major amputation rate	2(6.6%)	1(4.3%)	0
Limb salvage rate	28(93.3%)	22 (95.6%)	3/3(100%)

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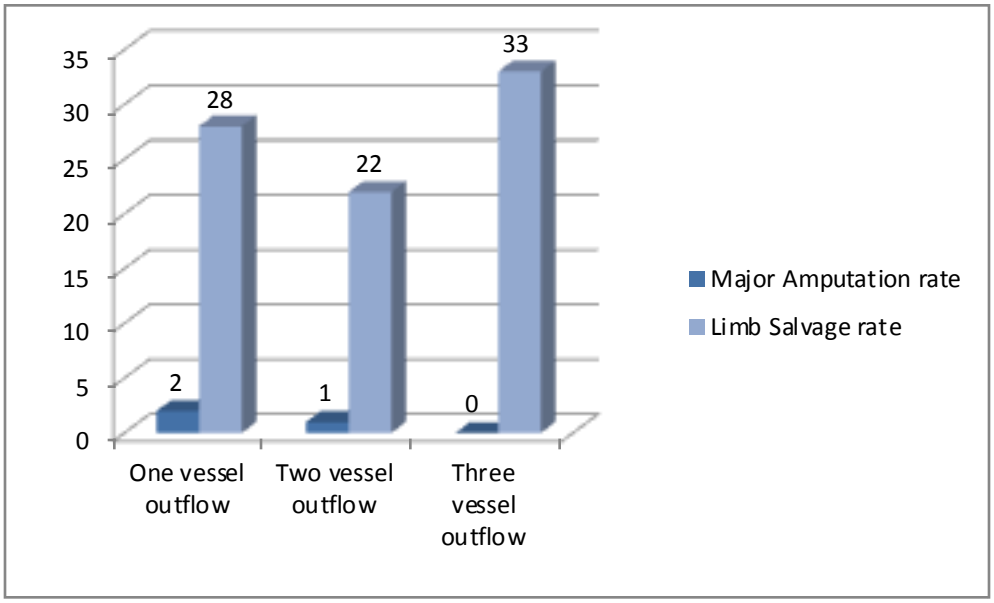
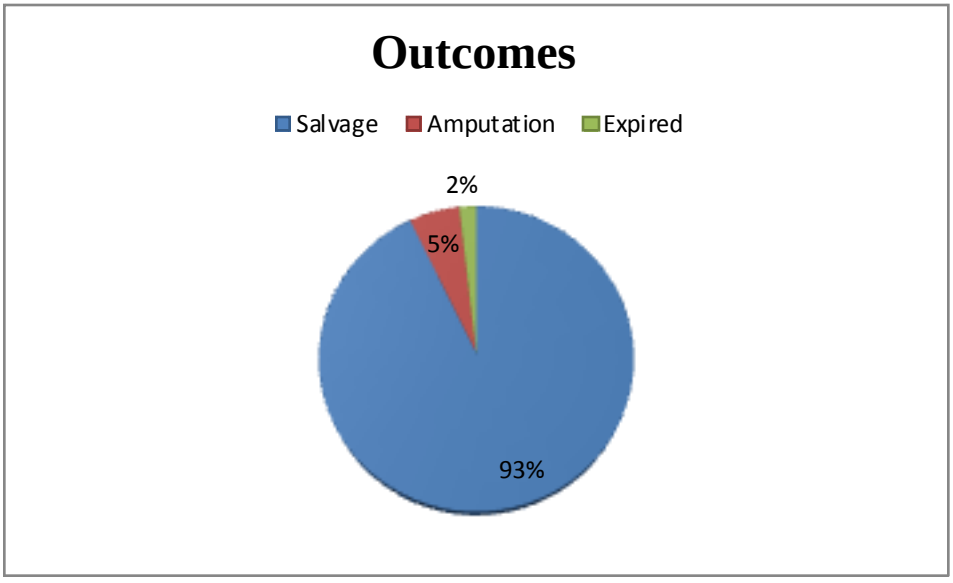


Outcomes

Outcomes		Frequency	Percent
	Limb Salvage	52	92.9
	Amputation	3	5.4
	Expired	1	1.8
	Total	56	100.0



Outcome analysis in relation to etiology

Outcomes		***Etiology***	
	ASO	**TAO**	**Arteritis**
Salvage	30	20	02
Amputation	03	0	0
Expired	01	0	0
Total	34	**20**	**2**

This high limb salvage rate when compared to the relatively low graft patency rates explains the collateral formation after bypass procedures especially when the graft was getting occluded gradually so that the limb survives. So these bypass procedures were considered as a bridge between critical limb ischemia period and collateral development so that limb ultimately survives

FACTORS INFLEUNCING GRAFT PATENCY AND LIMB SALVAGE

FACTORS		**PATENCY**	**LIMB SALVAGE**	**P value**
Gender	Male	44	50	0.064
	Female	2	2	0.003
Etiology	ASO	31	35	0.295
	TAO	11	16	0.884
	Arterits	1	2	0.648
	Hyper coagulable	0	0	0000
Redo	Failing	2	2	0.431
	Occluded	1	1	0.548
Outflow vessel	Prox popliteal	22	23	0.312
	Mid popliteal	2	1	0.201
	Distal popliteal	15	19	0.452
	Anterior Tibial	2	3	0.326
	Posterior Tibial	3	5	0.147
	TP Trunk	1	1	0.576
Level of surgery	Above knee Bypass	18	23	0.654
	Below knee Bypass	22	29	0.496
Conduit	RGSV	33	40	0.468
	ePTFE	8	11	0.248
	Composite	1	1	0.491
Graft Patency(1 year)	Primary	42	53	0.324
	PAP	44	52	0.510
	Cummulative	44	53	0.509
Ct Angio Runoff	Single	19	26	0.082
	Double	20	23	0.356
	Triple	3	3	0.567

DISCUSSION

Infrainguinal bypass surgery in Chronic Limb Ischemia, is the mainstay of therapeutic modality aimed at limb salvage. The outcome of surgery is the chief determinant of limb salvage, affected by many factors. These factors can be modifiable factors and non modifiable factors. Since 1949, when Kunlin [(4)] introduced the femoropopliteal bypass graft with Saphenous Vein, several centers have reported their results(Patency rates at 30 days have varied from 76% to 96%[1]. which is similar to this study.

This was a prospective study involving 56 patients who had undergone femoro popliteal bypass. Primary aim of this study was to determine factors affecting the graft patency .Mean age of the patient undergoing bypasses in this series was 51.7 yrs with range from 29to 74 yrs. Mean age of revascularization procedure in other series was 70 yrs [(2) (5).]

In the study group of 56 patients, only 3 were female and the remaining patients were male(n=53) . In other series of lower limb revascularization there were female patients in the range of 20%[2]to 35% [(3)]. The reason for this poor representation in the revascularization series might be due lower incidence of smoking in the females in our demography. Incidence of Thrombo Angiitis Obliterans(TAO) was higher in the males, whereas it has been only scarcely reported in females. Atherosclerotic Occlusive Disease is the commonest etiology in this study (67.8%) compared to the literature which

quotes an etiology of more than 95% .Thrombo Angiitis Obliterans (TAO)was almost non existent in their series as compared to this study which showed an occurrence of 28.5% remaining second most common etiology in this series [2] [3]. Indians were more prone to Thrombo angiitis obliterans because of the disease is more common among the low socioeconomic peoples who smoke beedis which has an unprocessed tobacco in it. The prevalence is about 14%-50%. Arterial disease in the diabetic patients in Indian population has also been quoted at a lower rate of only 2%-4%.

Smoking obviously forms a significant risk factor in the development of PAD as the incidence of smoking in this case series was 83.9 % and all were men. Incidence of CAD, CKD and diabetes mellitus was very high in patients with outflow via collaterals in CT Angiogram. In this study it was observed that diabetic mellitus does not adversely affect graft patency (as referred in journals - Influence of diabetes & other factors on graft patency (JVS ;August 2007) [7] ; [8] .

In this study one case of Atrial myxoma presented with CLI , had undergone femoro-proximal popliteal bypass surgery and graft was patent compared with literature [18] Vascular. 2005 Jul-Aug;13(4):222-9.In this review only 2 cases were reported to have presented with CLI, as a consequence of embolism due to atrial myxoma, a rarity, treated successfully.

Critical limb ischemia with minor or major tissue loss was the most common mode of presentation among the patients seeking medical attention in this series which was about 78%, non healing ulcer in another 9% of the patients and critical limb ischemia

with rest pain in 11% . In other studies of Distal artery revascularization and gangrene was the mode of presentation in 32%- 44% [2] [5]. (Eur J Surg 1994;160:17-25).

Clinical examination, ankle brachial index during the postoperative period help in detecting the hemodynamically significant lesion and highlighting the need for graft surveillance, Color Doppler has shown a major difference in detecting the early failing grafts even in asymptomatic patients, which is similar to this study protocol as compared to that of the study done by Keith D Calligaro and colleagues [6]. (Annals of vascular surgery -August 2001.

The overall patency rate for Femoropopliteal bypass using vein and PTFE in this study is 86.4% and 66.7% respectively when compared to other Literature (Patency rate for Femeropopliteal bypass with vein is 84 % and PTFE is 79 % both for proximal and distal bypass- Review of results in infrainguinal bypass Dalman - 2000) [10] . Low patency rate for PTFE in this study is due to low sample (n=13) since, we mostly prefer autogenous vein for most of infrainguinal bypass surgery.

The p values by Chi Square method for primary patency, Primary Assisted Patency (PAP) and cumulative patency rates with respect to the run off status at 1year were 0.324, 0.510 and 0.509 respectively and were statistically insignificant. In a study by Cvetanovski M. V., Jovev S. *et al* [12] , there was no significant difference in the graft patency rates between the groups concerning the lower limb tributaries and the runoff status. These results are in agreement with the results in a large number of studies, such as the study of Martin *et al.*

Even though the three vessels run off group in this study appears to be having high patency rates and no reintervention rates, the p values (0.870) were insignificant. This could be due to the very low number (n=3) in three vessels run off group when compared to one and two vessels run off group.

In our study the incidence of graft thrombosis in infrainguinal bypass for PTFE group (25.1%) than the vein group which is 20 % and is relatively similar compared to other studies by Michael Belkin et al where they reported failure rate of 28.6% for synthetic when compared to vein groups of 13.6% failure rate [9]. (Journal of vascular surgery ; February 1995 -Michael Belkin) In another study ,when Comparing Graft failure in this series was(n= 12)(23.2%) patients within a total of 56 patients in the post operative period to the similar study by Tina R. Desai, et al in Infrainguinal Bypass , they found a primary graft failure in 13% of their patients in group of 351 patients of all revascularization [1]. James M. Seeger et al reported forty-six graft failures occurred in 45 patients (21.4%) in 210 patients who studied about the potential predictors of infrainguinal bypass surgery [13]

In this study we used (n=1) PTFE – Vein composite graft with interposition vein cuff (St.Marys Boot) which is patent and it is used to avoid compliance mismatch between the prosthetic graft and native artery, which was patent in post operative period.

Prosthetic graft (PTFE) commonly used as an alternative to saphenous vein when autogenous vein is not available . PTFE graft is used along with a vein cuff improves the long term patency of the graft . Stonebridge et al in his randomized control study PTFE graft with vein cuff versus without cuff reported a 2 years patency of 52% versus 29%. Clearly indicated when PTFE graft used for the below knee bypass surgery vein

cuff was recommended [20]. Taylor patch was compare with St. Mary's boot reported equivalent results.

Post operative wound infection was in 7 % of the patients This low rate of wound infection was due to strict Theater Asepsis and preoperative antibiotics in all patients. The reported incidence of femoro popliteal graft infection in literatures was around 12% [11]. In the study by Cvetanovski M. V., Jovev S. *et al,* the major amputation rates were 4% [12] in comparision with our study it is n=3(5.4%). In the study by Cvetanovski M. V., Jovev S. *et al,* the mortality rate at 3rd month was 2% in comparision with our study it is n=1(1.78 %) who died of Myocardial Infarction .

The rate of limb salvage in patients with failed grafts was 83.3% fo 1 year, when compared to literature (only 50% at 2 yrs after failure. - Midwestern vascular surgical society Chicago September 2003) [22]

Postoperative mortality in the study was primarily caused by cardiac complications. This is not surprising considering the high incidence of coronary artery disease in patients with severe peripheral arterial occlusive disease [14] (Eur J Vasc Endovasc Surg 25:519–526, 2003). The mortality rate and the incidence of cardiac complications after primary amputation are at least as high or higher than after bypass grafting procedures, [15] and this is particularly true in patients with end-stage renal disease who undergo amputation (J Vasc Surg -1986;4:321-6) .

Prospective randomized trial by Kretschmer et al found that long-term anticoagulation therapy with dicumoral improved femoropopliteal bypass graft patency rates primarily for patients who underwent arterial reconstruction for limb salvage (those

most likely to have poor runoff).Postoperative anticoagulation therapy with heparin and aspirin followed by long-term anticoagulation therapy with warfarin and aspirin were found to improve the duration of graft patency and the limb salvage rate after autogenous vein infrainguinal bypass grafting for patients at high risk for graft failure. [21]

Anticoagulation therapy improves bypass graft patency and limb salvage in patients at high risk for infrainguinal bypass.In this study, selective patients with poor runoff and in few patients with TAO had heparin in the post operative period and followed by oral anticoagulation with aspirin and their PT/INR was maintained at 2-2.5 range.

Statin therapy is associated with improved patency in infrainguinal vein graft by preventing stenosis and occlusion. It is also due to because of Atheroprotective , Antithrombotic & Antiinflammatory (independent effect) apart from lipid lowering effect. (New England Society for vascular Surgery 2004 -Thomas a abbruzzese) [23] In our study we have observed less graft lesion in infrainguinal bypass vein graft who were on statins.

CONCLUSION

- Infrainguinal revasularisation surgery has acceptable graft patency and survival rates.
- Graft patency rates were not adversely affected by poor runoff vessels, and when there was a reformation of the popliteal artery even when the out flow vessels were not adequately visualized angiographically.
- High limb salvage rates when compared to the relatively low graft patency rates explains the collateral formation after bypass procedures.
- Femoro popliteal bypass grafting is still treatment of choice where endovascular facilities available for patients with disabling claudicants and in CLI especially with TASC C and D lesions.
- Patients with poor conduit quality, active tobacco use and LV dysfunction have poorer clinical outcome
- Graft surveillance is essential throughout the life to identify the failing graft and to intervene at appropriate time,to prolong the graft patency.

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INSTITUTIONAL ETHICAL COMMITTEE, STANLEY MEDICAL COLLEGE, CHENNAI-1

Title of the Work : Surveilance of Infra Inguinal Arterial By-pass graft – By
Principal Investigator : Dr. D. Ashok Kumar PG in M.ch (VS)
Designation : M.ch (VS)Post Graduate
Department : Department of Vascular Surgery
Government Stanley Medical College,
Chennai-1

The request for an approval from the Institutional Ethical Committee (IEC) was considered on the IEC meeting held on 18.04.2011 at the Modernized Seminar Hall, Stanley Medical College, Chennai-1 at 2PM

The members of the Committee, the secretary and the Chairman are pleased to approve the proposed work mentioned above, submitted by the principal investigator.

The Principal investigator and their team are directed to adhere to the guidelines given below:

1. You should inform the IEC in case of changes in study procedure, site investigator investigation or guide or any other changes.
2. You should not deviate form the area of the work for which you applied for ethical clearance.
3. You should inform the IEC immediately, in case of any adverse events or serious adverse reaction.
4. You should abide to the rules and regulation of the institution(s).
5. You should complete the work within the specified period and if any extension of time is required, you should apply for permission again and do the work.
6. You should submit the summary of the work to the ethical committee on completion of the work.

MEMBER SECRETARY,
IEC, SMC, CHENNAI

PROFORMA

NAME: _____ ADDRESS:_____

AGE: _____SEX:_____OCCUPATION:_____

CONTACT NO: _____DATE OF DISCH: _____

DIAGNOSIS

1.
2.

TASC: _____ SEGMENT:_____

HISTORY - Limb Upper / Lower RT / LT / BL

Pain	Discoloration
Claudication	Gangrene
Claudication distance	Swelling
Rest pain	H/o injury
Ulcer	

RISK FACTORS/ ASSOCIATED CONDITIONS

Smoking Yes/No Cig/bidi Years-____ Pack Years-_____

Alcohol	CVA
Hypertension	Diabetes
CAD	APD

TREATMENT HISTORY

CLINICAL EXAMINATION

Weight Body Mass Index BP -

Lungs

Heart

Abdomen

VASCULAR EXAM

Peripheral Pulses C B R F P DP PT

RT

LT

LOCAL- RT/ LT:

CVI

Ulcers

Gangrene

Discoloration

Edema/swelling/Motor weakness

	Ankle pressure	**Brachial pressure**	**ABI**
RT			
LT			

DOPPLER STUDIES (Date -)

	Fem	Pop	DP	PT	Br	Rad	Ul
RT							
LT							

INVESTIGATIONS

Hb gm% TLC / cumm DLC

Lipid profile TC HDL LDL VLDL TG

ECG; CAG / Echo/ : EF- % LV Fn RWMA

X-Ray Chest

Duplex Scan: Arterial/ Venous LL / UL RT / LT

DSA/ CT angio Nature of the lesion:

Reformation of popliteal A: AK/ BK segment.

Status of the distal vessels: Number of vessels reformed up to the foot – named vessel/ collaterals._____

MANAGEMENT

Medical/Surgical DATE**:** Anesthesia: GA / EA / SA / LA Surgeon:

Operation**:** _____

Procedure: Post op treatment**:** Inj.LMWH, T.ASA, T.Clopidogrel, Antibiotics, any other drugs according to the comorbidites.

Post-op course:

DISCHARGE STATUS

Ankle pressure Brachial pressure ABI

RT/LT/Doppler signals over the graft:_____

Discharge Advice: No smoking, T.ASA, T.Clopidogrel, other drugs prescribed by the cardiologist/ endocrinologist/ pulmonologist.

Follow up:

1/3/6/12 month: Date-

Ankle pressure Brachial pressure ABI

RT

LT

DOPPLER STUDIES / CDFI

Fem Pop DP PT Br Rad Ul

RT

LT

Requirement of secondary procedures like debridement with or without reconstruction/ amputation/ graft thrombectomy/ redo grafting….

Major events if any:

S.No	Name	Age	Sex	Etiology	Risk Factors	Clinical presentation	Pre op ABI	Angio site Occlusion	Distal Reformation	Type of Surgery	Inflow vessel site	Outflow vessel site	Distal Runoff	Conduit	Graft patency	Redo	Post op ABI	Improvement grade	Wound infection	Outcome
1	Subramani	50	1	1	Smoker;dyslip	great toe gangren	no flow	add hiatus; segmental	popliteal	1	mid sfa	1	2	1	1	2	0.9	3	2	1
2	Mukkammal	70	2	1	cad; arterits;dyslip	Non healing ulcer	no flow	add hiatus; segmental	post tibial	1	mid sfa	1	2	2	2	1	0.8	-2	1	1
3	Samson	50	1	2	smoker	ulcer foot	0.7	distal sfa	pta	2	prox sfa	3	1	1	1	2	1	3	2	1
4	Shankar	47	1	2	smoker	3rd toe gangrene	0.2	prox pop	mid at	2	distal sfa	4	1	1	1	2	0.7	2	2	1
5	Rajendran	59	1	1	dm;Dyslipidemia	5 th toe gangrene	no flow	add hiatus; segmental	prox pop	1	prox sfa	4	2	1	1	2	1	3	2	1
6	Kuppusamy	49	1	1	htn; smoker	great toe gangrene	0.30	distal sfa	mid pt	2	mid sfa	5	1	1	2	2	0.6	2	1	1
7	Govindasamy	59	1	1	dm; htn; smoker;dyslip	great toe gangrene	0.3	add hiatus; segmental	distal pop	2	midsfa	3	2	1	1	2	0.6	2	2	1
8	Babu	41	1	2	smoker	ulcer foot	0.2	sfa origin; segmental	midpop	2	cfa	3	1	1	1	2	1	3	2	1
9	Gopal	50	1	1	smoker;dyslip		0.45	add hiatus; segmental	prox pt	1	mid sfa	1	3	1	1	2	0.6	2	2	1
10	deena dayalan	65	1	1	dm;;dyslip	3rd toe gangrene	no flow	add hiatus; segmental	prox pop	1	prox sfa	1	3	2	1	2	1	3	2	1
11	Duraisamy	52	1	1	smoker	great toe gangrene	0.3	distal sfa	mid pt	2	mid sfa	5	1	1	1	2	0.5	2	2	1
12	rajendran	56	1	1	smoker;ihd;dyslip	ulcer leg	0.3	add hiatus; segmental	pta	2	mid sfa	5	1	1	1	2	0.6	-3	1	1
13	Perumal	57	1	1	dm; smoker;dyslip	ulcer foot	0.4	sfa origin; segmental	prox pop	1	cfa	1	2	2	1	2	0.6	-1	1	1
14	ravikumar	46	1	2	smoker;	toe gangrene	noflow	add hiatus; segmental	distal pop	2	cfa	3	1	1	3	2	0.7	-1	1	1
15	Rajavel	52	1	1	dm; htn; cva; smoker;dyslip	ulcer heel	0.28	sfa origin; segmental	prox pop	1	cfa	1	1	1	1	2	0.5	2	2	1
16	Muthu	72	1	1	dm;;dyslip	3rd toe gangrene	no flow	add hiatus; segmental	prox pop	1	prox sfa	1	2	2	3	2	0.5	-3	2	1
17	Krishnaiaha	52	1	1	smoker	great toe gangren	no flow	add hiatus; segmental	popliteal	1	mid sfa	1	2	2	1	2	0.9	3	2	1
18	Valliyammal	61	2	1	dm; htn; ihd;dyslip		0.35	cfa; segmental	sfa; distal pop	1	cfa	1	1	1	1	2	0.45	2	1	3
19	Dayalan	52	1	1	smoker;dyslip	great toe gangrene	no flow	add hiatus; segmental	popliteal	1	mid sfa	1	1	1	1	2	0.7	3	2	1
20	Sudhakar	45	1	3	smoker	great toe	0.5	midpop segmental	distalpop	2	distal sfa	3	1	3	1	2	0.6	2	1	1
21	Jayakumar	48	1	2	smoker		0.45	add hiatus; segmental	prox pt	1	mid sfa	5	2	1	1	2	0.6	2	2	1
22	Kuppan	65	1	1	smoker; dm;dyslip	ulcer webspace	0.2	sfa origin	prox pop	1	cfa	1	2	1	1	2	0.5	2	2	1

S.No	Name	Age	Sex	Etiology	Risk Factors	Clinical presentation	Pre op ABI	Angio site Occlusion	Distal Reformation	Type of Surgery	Inflow vessel site	Outflow vessel site	Distal Runoff	Conduit	Graft patency	Redo	Post op ABI	Improvement grade	Wound infection	Outcome
23	Jayavel	65	1	1	smoker; dm	ulcer webspace	0.2	sfa origin	prox pop	1	cfa	1	2	1	2	1	no flow	-3	2	2
24	Babu	57	1	1	dm; htn	ulcer foot	0.2	sfa origin; segmental	prox pop	1	cfa	1	1	1	1	2	0.5	1	2	1
25	Narasiaha	63	1	1	smoker	2nd toe gangrene	0.2	add hiatus	pt	2	proxsfa	2	1	1	3	2	no flow	-3	2	2
26	Sakunthala	74	2	1	dm; htn; ihd		0.35	cfa; segmental	sfa; distal pop	2	cfa	3	1	1	1	2	0.45	2	1	1
27	ravi	47	1	2	smoker; cad;dyslip	ulcer toe tip	0.5	add hiatus; segmental	ant tibial	2	prox pop	4	1	1	3	2	0.7	2	2	1
28	Aliyaar	54	1	1	dm;smoker;dyslip	2nd toe gangrene	no flow	add hiatus; segmental	prox pop	1	prox sfa	1	2	1	1	2	1	2	2	1
29	Ambedkar	38	1	2	smoker;	gangrene 4 th toe	0.2	add hiatus	prox pop	1	cfa	1	1	1	1	2	0.5	2	2	1
30	Jeganathan	65	1	1	smoker	toes gangrene	0.3	mid pop; segmental	post tibial	1	prox pop	1	2	2	1	2	0.7	2	2	1
31	Marimuthu	29	1	2	smoker	great toe gangrene	0.2	add hiatus; segmental	midpop	2	mid sfa	3	1	1	3	2	0.6	2	1	1
32	Palanisamy	49	1	1	smoker; htn; Atrial myxoma;dyslip	ulcer heel	0.28	sfa origin; segmental	prox pop	1	cfa	1	2	2	1	2	0.5	2	2	1
33	Gopal	71	1	1	smoker; dm;dyslip	gangrene 3 rd toe	0.2	sfa origin; segmental	prox pop	1	cfa	1	3	2	2	2	0.5	3	2	1
34	Anbu	35	1	2	smoker	ulcer foot	0.3	add hiatus; segmental	prox pop	2	mid sfa	2	2	1	1	2	0.6	2	1	1
35	Subbaiha	72	1	1	smoker	ulcer foot	0.2	sfa origin	distal pop	2	cfa	3	1	1	1	2	0.8	2	2	1
36	Nagan	55	1	1	htn; smoker	little toe gangren	0.25	add hiatus; segmental	tptrunk	2	mid sfa	5	1	1	2	2	1	3	2	1
37	Rajkumar	49	1	1	dm; htn	ulcer foot	0.2	sfa origin	distal pop	2	cfa	3	2	1	1	2	0.8	2	2	1
38	Venkatesaiha	50	1	1	dm	toes gangrene	0.3	sfa origin	prox pop	2	cfa	3	2	1	1	2	0.6	2	2	1
39	Rajendran	51	1	1	dm; htn; smoker	great toe gangrene	0.4	add hiatus; segmental	distal pop	2	midsfa	3	2	1	1	2	0.6	2	2	1
40	Duraisamy	38	1	2	smoker	ulcer foot	0.3	sfa origin; segmental	midpop	2	cfa	3	1	1	1	2	0.8	3	2	1
41	Arul	50	1	1	dm;smoker	toes gangrene	0.25	sfa origin	prox pop	2	cfa	3	2	1	1	2	0.6	2	2	1
42	Swaminathan	51	1	2	smoker	great toe gangren	0.16	mid pop	no distal reformation	2	prox pop	5	1	1	1	2	0.6	2	2	1
43	Manohar	44	1	2	smoker	great toe gangren	no flow	add hiatus; segmental	popliteal	1	mid sfa	1	2	1	1	2	0.7	2	2	1
44	Balakrishnan	56	1	1	smoker;dyslip	ulcer foot	0.5	distal sfa	popliteal	1	prox sfa	1	3	2	1	2	1	3	2	1
45	Shankaran	51	1	1	dm;smoker	3rd toe gangrene	no flow	add hiatus; segmental	prox pop	1	prox sfa	1	2	1	1	2	1	2	1	1
46	Chinnasamy	45	1	2	smoker	great toe	0.5	midpop segmental	distalpop	2	distal sfa	3	1	1	1	2	0.7	2	2	1

S.No	Name	Age	Sex	Etiology	Risk Factors	Clinical presentation	Pre op ABI	Angio site Occlusion	Distal Reformation	Type of Surgery	Inflow vessel site	Outflow vessel site	Distal Runoff	Conduit	Graft patency	Redo	Post op ABI	Improvement grade	Wound infection	Outcome
47	ganesan	65	1	1	dm;smoker;dyslip	toes gangrene	0.25	sfa origin	prox pop	2	cfa	3	2	1	1	2	0.6	2	2	1
48	Baskar	45	1	1	dm;smoker;dyslip	ulcer foot	0.16	sfa origin	prox pop	1	cfa	1	1	1	2	1	0.6	2	1	1
49	Selvam	48	1	2	smoker;	gangrene 3 rd toe	0.2	add hiatus	prox pop	1	cfa	1	2	2	1	2	0.5	2	2	1
50	Vadivelu	63	1	1	dm;smoker;dyslip	3rd toe gangrene	no flow	add hiatus; segmental	prox pop	1	prox sfa	1	1	1	3	2	0.7	2	2	1
51	abdulla	63	1	1	smoker	great toe gangrene	0.2	add hiatus	pt	2	proxsfa	2	1	1	1	2	no flow	-3	2	2
52	kamaraj	46	1	2	smoker	ulcer foot	0.4	midpop segmental	distalpop	2	distal sfa	3	1	1	1	2	0.7	2	2	1
53	Karunanidhi	36	1	3	smoker	great toe gangren	no flow	add hiatus; segmental	popliteal	2	mid sfa	3	1	1	3	2	0.9	3	2	1
54	Murugesan	55	1	1	htn; smoker	little toe gangren	0.2	add hiatus; segmental	tptrunk	2	mid sfa	6	1	1	1	2	0.9	3	2	1
55	Soundarajan	61	1	1	dm; htn; smoker	great toe gangrene	0.3	add hiatus; segmental	distal pop	1	midsfa	3	2	2	1	2	0.6	2	2	1
56	kumar	44	1	2	smoker; cad;dyslip	ulcer toe tip	0.5	add hiatus; segmental	ant tibial	2	distal sfa	3	1	1	3	2	0.7	1	2	1

	M=1	ASO=1							AKB=1		prox pop=1	single vessel=1	RGSV=1	Patent=1	PAP=1			Yes=1	Yes=1	
	F=2	TAO=2							BKB=2		distal pop=2	double vessel=2	PTFE=2	Failing=2	No Redo=2			No=2	No=2	
		Arteritis=3									midpop=3	triple vessel=3	Coposite=3	Occluded=3					Expired=3	
											mid at=4									
											mid pt=5									
											tptrunk=6									

OUTCOME ANALYSIS AND SURVEILLANCE OF INFRA INGUINAL ARTERIAL BYPASS GRAFT

BACK GROUND

In Crtical Limb Ischemia, Infrainguinal bypass surgery is the mainstay of therapeutic interventions aimed at limb salvage. The outcome of surgery is the chief determinant of limb salvage and is affected by multiple factors. The graft patency rates have been related to clinical severity of ischemia, distal run-off,patients risk factors, and Diabetes.

This study is planned to review the factors that will influence the outcome of infrainguinal bypass and to identify those factors that are modifiable, and will help in improving the outcome of the procedures ,improve the patency of the graft and limb salvage rate.

AIM

To assess early postoperative outcomes in patients undergoing Infrainguinal bypass surgery ,to study the factors affecting the outcomes and to identify failing graft.

METHODS AND MATERIALS

It is Prospective study in 56 patients from January 2010 to January 2012.Case records and angiograms of patients who underwent femoropopliteal bypass procedures. CLI and incapicitating claudication is the main indication for surgery. Data pertaining to patient risk factors and co-morbidities were evaluated. CT angio performed in all patients to assess the

occlusive pattern, status of popliteal artery and run off status and the lesions were classified as per TASC 2007 classification. Infrainguinal bypass surgery were considered for all patients.

Standard operative procedures were followed. Postoperatively all patients were given Plain Heparin or LMWH for 5 days & Tab. Aspirin 150mg OD & Tab. Clopidogrel 75mg and other drugs as per their co-morbidities. Graft surveillance was done by symptomatic analysis of rest pain status, palpable popliteal pulse and distal pulses, examination with handheld Doppler for signals and with Pre and post operative ABI. All patients were followed from the day of surgery to the end of 12^{th} month.Statistical analysis of the graft patency rates were calculated with respect to the CT Angio run off status,risk factors, etiolgical factors,and limb salvage rate.

RESULTS

In this study, most of the patients had presented at the age around 40 to 60 yrs. Smoking obviously forms a significant risk factor in the development of PAD as the incidence of smoking in this case series was 83.3%.Toe gangrene is commonest clinical presentation is58.9%.ASO is commonest etiology of 67.8%. Incidence of CAD, CKD and diabetes mellitus was very high in patients with outflow via collaterals. The incidence of CLI patients with single vessel runoff group are 53.5%, double vessel runoff group are 41.07% and three vessels run off group is 5.3%.Among total of 56 patients, femoro popliteal bypass forms the common form of bypass with 43 patients compared to femoro distal bypass in other patients. Among various post operative complications minor amputations being 33.9% is the commonest complication. . Patients with wound infection in our series was 12.5%.

During the post operative follow up period one patient expired in the early postoperative period due to myocardial infarction. In our study group infra inguinal arterial bypass surgery, out

of total 56 grafts, for 43patients RGSV and 13 (1 = Composite graft) PTFE grafts used. Graft occlusion rate is 16.07% and Graft failing rate is 10.7%.Primary patency rate of graft at the end of one year is 80 % (n=44) .Graft thrombosis rate in this study is 16.36% (n=9). Six grafts were identified during their failing stage in the study, out of which 3 patients underwent Redo bypass surgery (PAP 82.1%).Among redo group for 2 , grafts patency restored and their limbs salvaged and 1 graft occluded subsequently and resulted in limb amputation .

The p values for primary patency, cumulative patency rates with respect to the run off status at 12^{th} month were 0.324, 0.509 respectively and were statistically insignificant.Primary assisted patency rate in this study is 82.1 %. Limb salvage rate was 94.54%. Failing graft in this study is 10.9% (n=6). Major Amputation rate in this study is (5.3 %).

The graft patency was compared in relation to etiological factors in 56 patients. In atherosclerosis group of 38 grafts used , out them n=29 had patent grafts ,n=4 occluded and n=6 were failing . In thromboangitis obliterans n=11 were patent and n=4 were occuled . In Arteritis group n=1 patent and n=1 occuled . TAO and arteritis had increased risk of graft occlusion during the follow up. The occurrence of graft stenosis or occlusion is more common in patients who underwent infragenicular bypasses than above knee bypass. In this study one case of Atrial myxoma presented with CLI , had undergone femoro-proximal popliteal bypass surgery and graft was patent compared with literature [18] Vascular. 2005 Jul-Aug;13(4):222-9.

The rate of limb salvage in patients with failed grafts was 83.3% fo 1 year, when compared to literature (only 50% at 2 yrs after failure. - Midwestern vascular surgical society Chicago September 2003).

CONCLUSION

- Infrainguinal revasularisation surgery has acceptable graft patency and survival rates.
- Graft patency rates were not adversely affected by poor runoff vessels, and when there was a reformation of the popliteal artery even when the out flow vessels were not adequately visualized angiographically.
- High limb salvage rates when compared to the relatively low graft patency rates explains the collateral formation after bypass procedures.
- Femoro popliteal bypass grafting is still treatment of choice where endovascular facilities available for patients with disabling claudicants and in CLI especially with TASC C and D lesions.
- Patients with poor conduit quality, active tobacco use and LV dysfunction have poorer clinical outcome
- Graft surveillance is essential throughout the life to identify the failing graft and to intervene at appropriate time,to prolong the graft patency.

KEY WORDS

Infrainguinal revasularisation, Graft surveillance, Graft patency,Conduit, CT angio, Primary Assited Patency.